PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : G01N 33/52, 33/04

A2

(11) International Publication Number: **WO 00/65348**

(43) International Publication Date: 2 November 2000 (02.11.00)

(21) International Application Number: PCT/US00/11208

(22) International Filing Date: 26 April 2000 (26.04.00)

(30) Priority Data:

09/299,399	26 April 1999 (26.04.99)	US
09/517,441	2 March 2000 (02.03.00)	US
09/517,481	2 March 2000 (02.03.00)	US

(71) Applicant: THE PROCTER & GAMBLE COMPANY [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).

(72) Inventors: ROE, Donald, Carroll; 6324 Emberwood Court, West Chester, OH 45069 (US). MUSCAT, Andreas; Avrillestr. 7, D–65824 Schwalbach (DE). HAMMONS, John, Lee; 7379 Dust Commander Drive, Hamilton, OH 45011 (US). OSBORN, Thomas, Ward, III; 640 Windings Lane, Cincinnati, OH 45220 (US). HILL, Donna, R.; 104 Sunset Avenue, Erlanger, KY 41018 (US). PEARCE, Anne, Marie; 3633 Zumstain Avenue, Cincinnati, OH 45208 (US).

(74) Agents: REED, T., David et al.; The Procter & Gamble Company, 5299 Spring Grove Avenue, Cincinnati, OH 45217–1087 (US).

(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), DM, EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

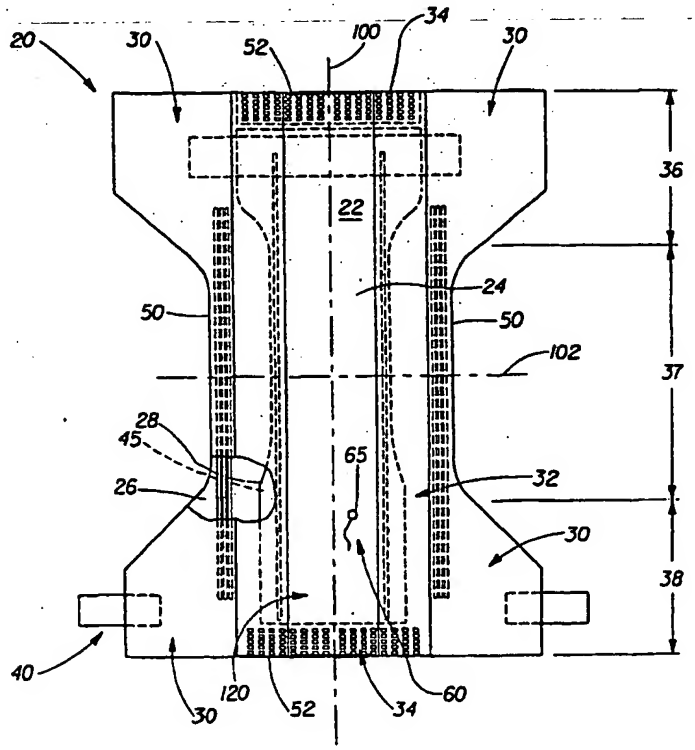
Published

Without international search report and to be republished upon receipt of that report.

(54) Title: DISPOSABLE ARTICLES AND OTHER ARTICLES COMPRISING A DETECTION DEVICE

(57) Abstract

A disposable article to be fitted to a wearer and other types of articles having a detection device, such as a diagnostic panel that may, in one set of embodiments, include at least one biosensor, each including at least one bio-recognition element. The biosensor is adapted to detect a target biological analyte in body substances, and on/or through the wearer's skin. The diagnostic panel may be adapted to determine the physical condition or state of well being of a mammal, or the cause of a particular disease state, such as diarrhea, vaginal infections, sexually transmitted diseases ("STD's"), and other diseases, and to signal the caretaker, the wearer, or an actuator of the occurrence. Examples of physical conditions of the state of well being include, but are not limited to, ovulation and the onset of menstruation.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

DISPOSABLE ARTICLES AND OTHER ARTICLES COMPRISING A DETECTION DEVICE

FIELD OF THE INVENTION

The present invention relates to disposable articles and other types of articles having a detection device, such as a diagnostic panel that may, in one set of embodiments, include biosensors having a bio-recognition element that detects microorganisms and/or other biomolecules present in a mammalian body, and more particularly an article that detects microorganisms and/or other biomolecules that may be present in body substances, and on/or through the skin. The present invention also relates to other types of detection devices, and methods of using the same.

BACKGROUND OF THE INVENTION

Today, disposable articles, such as diapers, adult incontinence briefs, sanitary napkins and tampons, are widely used for daily purposes and in infant and toddler care and in the care of incontinent or menstruating adults as a means of containing, isolating and disposing of bodily wastes. These articles have generally replaced reusable, washable cloth garments as the preferred means for these applications because of their convenience and reliability. The disposable articles respond to a defecation, urination or discharge event by absorbing or containing bodily wastes deposited on the article. Some disposable articles also signal a defecation, urination or discharge event after it has occurred (e.g., wetness indicators, temperature change detection). Other disposable absorbent articles known in the art comprise a chemically reactive means to detect various substances in the wearer's waste(s). However, none of these specifically detect target potentially pathogenic microorganisms such as bacteria, viruses, fungi, and parasites (e.g., protozoans) and/or related biomolecules, all of which require a high

degree of selectivity (i.e., specificity) and sensitivity versus purely chemical agents. Additionally, the articles do not predict when a health-related event is about to occur and signal wearer or caregiver that prophylactic or remedial action is required prior to the onset of clinically observable symptoms.

SUMMARY OF THE INVENTION

The present invention is directed to disposable articles and other articles comprising a detection device, such as a biosensor diagnostic panel that may, in one set of embodiments, include at least one biosensor and at least one bio-recognition element. The biosensor is adapted to detect a target biological analyte in body substances released from a mammalian body (including bodily fluids, bodily waste, other bodily discharges) and on/or through the skin. The disposable article may comprise a diagnostic panel adapted to determine the physical conditions or state of well being of a mammal, or the cause of a particular disease state, such as diarrhea, vaginal infections, sexually transmitted diseases ("STD's"), and other diseases, and to signal the caretaker, the wearer, or an actuator of the occurrence. Examples of physical conditions or the state of well being include, but are not limited to ovulation and the onset of menstruation.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1A is a plan view of a diaper embodiment of the present invention in a flat-out state with portions of the structure being cut-away to more clearly show the construction of the diaper.

Figure 1B is a plan view of an example of a diagnostic panel having two biosensors thereon.

Figure 1C is a cross-sectional view of the diagnostic panel shown in Figure 1B, taken along lines 1C-1C of Fig. 1B.

Figure 1D is a plan view of an example of a diagnostic panel similar to that shown in Figs. 1B and 1C, but having a wiping mechanism provided therewith.

Figure 1E is a cross-sectional view of the diagnostic panel shown in Figure 1D, taken along lines 1E-1E of Fig. 1D.

Figure 2 shows a perspective view of a bodily waste isolation device for the present invention in a compressed state before activation.

Figure 2A shows a sectional view taken along line 2A-2A of Figure 2.

Figure 3A shows an ideal output function of a discontinuous responsive system of the present invention having a single threshold level.

Figure 3B shows an ideal output function of a discontinuous responsive system of the present invention having multiple threshold levels.

Figure 4A shows an exemplary output function of a discontinuous responsive system of the present invention along with the first, second and third derivatives of the output function.

Figure 4B shows a transfer function of a control system having a series of first order lags having an equal time constant.

Figures 5A and 5B show an embodiment of a responsive system of the present invention including an electrically sensitive gel.

Figures 6A, 6B and 6C show another embodiment of a responsive system of the present invention including an electrically sensitive gel.

Figure 7 is a perspective view of a waste bag embodiment of the present invention.

Figure 8 is a perspective view of an absorbent article including a waste bag.

Figure 9 is a plan view of a panty liner embodiment of the present invention.

Figure 9A is a cross-sectional view of the panty liner embodiment shown in Fig. 9, taken along line 9A-9A of Fig. 9 showing the diagnostic panel thereon in greater detail.

Figure 10 shows a colorimetric indicator embodiment that can be used to detect the quantity of the microorganisms, biomolecules, or other substances of interest.

Figure 11 shows a color comparison chart that can be used to indicate the quantity of the substance present.

Figure 12 is a plan view of a sanitary napkin embodiment of the present invention.

Figure 13 is a plan view of an interlabial device embodiment of the present invention.

Figure 14 is a cross-sectional view of the interlabial device shown in Fig. 13, taken along line 14-14 of Fig. 13.

Figure 15 is a side view of the interlabial device shown in Fig. 13.

Figure 16 is a side view of the interlabial device shown in Fig. 13 which shows how the interlabial device is held for insertion into the space between the wearer's labia.

Figure 17 shows how the interlabial device is worn relative to the wearer's body.

Figure 18 is a perpective view of a tampon embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

As used herein, the term "absorbent article" refers to devices which absorb and contain body exudates, and more specifically, refers to devices which are placed against or in proximity to the body of the wearer to absorb and contain the various exudates discharged from the body. The term "disposable" is used herein to describe absorbent articles which generally are not intended to be laundered or otherwise restored or reused as an absorbent article (i.e., they are intended to be discarded after a single use and, preferably, to be recycled, composted or otherwise disposed of in an environmentally compatible manner). (As used herein, the term "disposed" is used to mean that an element(s) of the article is formed (joined and positioned) in a particular place or position as a unitary structure with other elements of the article or as a separate element joined to another element of the article. As used herein, the term "joined" encompasses configurations whereby an element is directly secured to another element by affixing the element directly to the other element, and configurations whereby an element is indirectly secured to another element by affixing the element to intermediate member(s) which in turn are affixed to the other element.) A "unitary" absorbent article refers to absorbent articles which are formed of separate parts united together to form a coordinated entity so that they do not require separate manipulative parts like a separate holder and liner. As used herein, the term "body substances" refers to substances released from a mammalian body. The term "body substances" includes bodily fluids and

biological fluid such as vaginal discharges. menses. sweat and saliva, bodily waste such as urine and feces, and any other bodily discharge such as tears and ejaculate.

One embodiment of an absorbent article that may be provided with a biosensor diagnostic panel according to the present invention is a unitary disposable absorbent article, such as the diaper 20 shown in Figure 1. As used herein, the term "diaper" refers to an absorbent article generally worn by infants and incontinent persons about the lower torso. The present invention is also applicable to other absorbent or non-absorbent articles such as incontinence briefs, incontinence undergarments, absorbent inserts, diaper holders and liners, colostomy bags for a natural or artificial anus, feminine hygiene devices (which include, but are not limited to panty liners, sanitary napkins, interlabial devices and tampons), wipes. disposable towels, tissues (including toilet tissue), articles with which a saliva sample can be taken, water absorbing articles, oil absorbing articles, spill cleanup bags, desiccant bags, disposable mops, bandages, therapeutic wraps, supports, disposable heating pads and the like.

Figure 1 is a plan view of the diaper 20 in a flat-out, state with portions of the structure being cut-away to more clearly show the construction of the diaper 20. The portion of the diaper 20 which faces the wearer is oriented towards the viewer. As shown in Figure 1, the diaper 20 preferably comprises a liquid pervious topsheet 24; a liquid impervious backsheet 26; an absorbent core 28, which is preferably positioned between at least a portion of the topsheet 24 and the backsheet 26; side panels 30; elasticized leg cuffs 32; an elastic waist feature 34; and a fastening system generally designated 40. Diaper 20 is shown in Figure 1 to have a first waist region 36, a second waist region 38 opposed to the first waist region 36 and a crotch region 37 located between the first waist region and the second waist region. The periphery of the diaper 20 is defined by the outer edges of the diaper 20 in which the longitudinal edges 50 run generally parallel to the longitudinal centerline 100 of the diaper 20 and the end edges 52 run between the longitudinal edges 50 generally parallel to the lateral centerline 102 of the diaper 20.

The chassis 22 of the diaper 20 comprises the main body of the diaper 20. The chassis 22 comprises at least a portion of the absorbent core 28 and preferably an outer

covering layer including the topsheet 24 and the backsheet 26. If the absorbent article comprises a separate holder and a liner, the chassis 22 generally comprises the holder and the liner. (For example, the holder may comprise one or more layers of material to form the outer cover of the article and the liner may comprise an absorbent assembly including a topsheet, a backsheet, and an absorbent core. In such cases, the holder and/or the liner may include a fastening element which is used to hold the liner in place throughout the time of use.) For unitary absorbent articles, the chassis 22 comprises the main structure of the diaper with other features added to form the composite diaper structure. While the topsheet 24, the backsheet 26, and the absorbent core 26 may be assembled in a variety of well known configurations, preferred diaper configurations are described generally in U.S. Pat. No. 3,860,003 entitled "Contractible Side Portions for Disposable Diaper" which issued to Kenneth B. Buell on January 14, 1975; U.S. Pat. No. 5,151,092 issued to Buell on September 9, 1992; and U.S. Pat. No. 5,221,274 issued to Buell on June 22, 1993; and U.S. Pat. No. 5,554,145 entitled "Absorbent Article With Multiple Zone Structural Elastic-Like Film Web Extensible Waist Feature" which issued to Roe et al. on September 10, 1996; U.S. Pat. No. 5,569,234 entitled "Disposable Pull-On Pant" which issued to Buell et al. on October 29, 1996; U.S. Pat. No. 5,580,411 entitled "Zero Scrap Method For Manufacturing Side Panels For Absorbent Articles" which issued to Nease et al. on December 3, 1996; and U.S. Patent Application Serial No. 08/915,471 entitled "Absorbent Article With Multi-Directional Extensible Side Panels" filed August 20, 1997 in the name of Robles et al.; each of which is incorporated herein by reference.

The backsheet 26 is generally that portion of the diaper 20 positioned adjacent the garment facing surface 45 of the absorbent core 28 which prevents the exudates absorbed and contained therein from soiling articles which may contact the diaper 20, such as bedsheets and undergarments. The backsheet 26 may be joined to the topsheet 24, the absorbent core 28 or any other element of the diaper 20 by any attachment means known in the art. Suitable backsheet films include those manufactured by Tredegar Industries Inc. of Terre Haute, IN and sold under the trade names X15306, X10962 and X10964. Other suitable backsheet materials may include breathable materials such as woven webs, nonwoven webs, composite materials such as film-coated nonwoven webs, and

microporous films such as manufactured by Mitsui Toatsu Co., of Japan under the designation ESPOIR NO; EXXON Chemical Co., of Bay City, TX, under the designation EXXAIRE; or monolithic films such as manufactured by Clopay Corporation, Cincinnati, OH under the name HYTREL blend P18-3097. Such breathable composite materials are described in greater detail in PCT Application No. WO 95/16746, published on June 22, 1995 in the name of E. I. DuPont; copending U.S. Patent No. 5,865,823 issued to Curro on February 2, 1999; U.S. Pat. No. 5,571,096 issued to Dobrin et al. on November 5, 1996. Each of these references is hereby incorporated by reference herein.

The backsheet 26, or any portion thereof, may be elastically extensible in one or more directions. In one embodiment, the backsheet 26 may comprise a structural elastic-like film ("SELF") web. A structural elastic-like film web is an extensible material that exhibits an elastic-like behavior in the direction of elongation without the use of added elastic materials. SELF webs suitable for the present invention are described in U.S. Patent No. 5,518,801 entitled Web Materials Exhibiting Elastic-Like Behavior, which issued to Chappell, et, al. on May 21, 1996, which is incorporated herein by reference. In alternate embodiments, the backsheet 26 may comprise elastomeric films, foams, strands, or combinations of these or other suitable materials with nonwovens or synthetic films.

The topsheet 24 is preferably compliant, soft feeling, and non-irritating to the wearer's skin. A suitable topsheet 24 may be manufactured from a wide range of materials, such as porous foams; reticulated foams; apertured plastic films; or woven or nonwoven webs of natural fibers (e.g., wood or cotton fibers), synthetic fibers (e.g., polyester or polypropylene fibers), or a combination of natural and synthetic fibers. If the topsheets include fibers, the fibers may be spunbond, carded, wet-laid, meltblown, hydroentangled, or otherwise processed as is known in the art. One suitable topsheet 24 comprising a web of staple length polypropylene fibers is manufactured by Veratec, Inc., a Division of International Paper Company, of Walpole, Massachusetts under the designation P-8.

Suitable formed film topsheets are described in U.S. Pat. No. 3,929,135, entitled "Absorptive Structures Having Tapered Capillaries", which issued to Thompson on

December 30, 1975; U.S. Pat. No. 4,324,246 entitled "Disposable Absorbent Article Having A Stain Resistant Topsheet", which issued to Mullane, et al. on April 13, 1982; U.S. Patent 4,342,314 entitled "Resilient Plastic Web Exhibiting Fiber-Like Properties", which issued to Radel, et al. on August 3, 1982; U.S. Pat. No. 4,463,045 entitled "Macroscopically Expanded Three-Dimensional Plastic Web Exhibiting Non-Glossy Visible Surface and Cloth-Like Tactile Impression", which issued to Ahr, et al. on July 31, 1984; and U.S. Pat. No. 5,006,394 "Multilayer Polymeric Film" issued to Baird on April 9, 1991. Other suitable topsheets 24 are made in accordance with U.S. Pat. Nos. 4,609,518 and 4,629,643 which issued to Curro et al. on September 2, 1986 and December 16, 1986, respectively, and in U.S. Patent 4,695,422 and U.S. Patent 5,520,875, all of which are incorporated herein by reference. Such formed films are available from The Procter & Gamble Company of Cincinnati, Ohio as "DRI-WEAVE" and from Tredegar Corporation of Terre Haute, Indiana as "CLIFF-T."

The topsheet 24 may be made of a hydrophobic material or may be treated to be hydrophobic in order to isolate the wearer's skin from liquids contained in the absorbent core 28. If the topsheet 24 is made of a hydrophobic material, preferably at least the upper surface of the topsheet 24 is treated to be hydrophilic so that liquids will transfer through the topsheet more rapidly. The topsheet 24 can be rendered hydrophilic by treating it with a surfactant or by incorporating a surfactant into the topsheet. Suitable methods for treating the topsheet 24 with a surfactant include spraying the topsheet 24 material with the surfactant and immersing the material into the surfactant. A more detailed discussion of such a treatment and hydrophilicity is contained in U.S. Pat. No. 4,988,344 entitled "Absorbent Articles with Multiple Layer Absorbent Layers" issued to Reising, et al. on Jan. 29, 1991 and U.S. Pat. No. 4,988,345 entitled "Absorbent Articles with Rapid Acquiring Absorbent Cores" issued to Reising on Jan. 29, 1991. A more detailed discussion of some suitable methods for incorporating surfactant in the topsheet can be found in U.S. Statutory Invention Registration No. H1670, published on July 1, 1997 in the names of Aziz et al. Each of these references is hereby incorporated by reference herein.

Any portion of the topsheet 24 or other components of the article may be coated with a lotion as is known in the art. Examples of suitable lotions include those described in U.S. Pat. Nos. 5,607,760 entitled "Disposable Absorbent Article Having A Lotioned Topsheet Containing an Emollient and a Polyol Polyester Immobilizing Agent" which issued to Roe on March 4, 1997; U.S. Pat. No. 5,609,587 entitled "Diaper Having A Lotion Topsheet Comprising A Liquid Polyol Polyester Emollient And An Immobilizing Agent" which issued to Roe on March 11, 1997; U.S. Pat. No. 5,635,191 entitled "Diaper Having A Lotioned Topsheet Containing A Polysiloxane Emollient" which issued to Roe et al. on June 3, 1997; and U.S. Pat. No. 5,643,588 entitled "Diaper Having A Lotioned Topsheet" which issued to Roe et al. on July 1, 1997. The lotion may function alone or in combination with another agent as the hydrophobizing treatment described above. The topsheet may also include or be treated with antibacterial agents, some examples of which are disclosed in PCT Publication No. WO 95/24173 entitled "Absorbent Articles Containing Antibacterial Agents in the Topsheet For Odor Control" which was published on September 14, 1995 in the name of Theresa Johnson. Further, the topsheet 24, the backsheet 26 or any portion of the topsheet or backsheet may be embossed and/or matte finished to provide a more cloth like appearance.

The absorbent core 28 may comprise any absorbent material which is generally compressible, conformable, non-irritating to the wearer's skin, and capable of absorbing and retaining liquids such as urine and other certain body exudates. The absorbent core 28 may be manufactured in a wide variety of sizes and shapes (e.g., rectangular, hourglass, "T"-shaped, asymmetric, etc.) and may comprise a wide variety of liquid-absorbent materials commonly used in disposable diapers and other absorbent articles such as comminuted wood pulp, which is generally referred to as airfelt. Examples of other suitable absorbent materials include creped cellulose wadding; meltblown polymers, including coform; chemically stiffened, modified or cross-linked cellulosic fibers; tissue, including tissue wraps and tissue laminates; absorbent foams; absorbent sponges; superabsorbent polymers; absorbent gelling materials; or any other known absorbent material or combinations of materials.

The configuration and construction of the absorbent core 28 may also be varied (e.g., the absorbent core(s) or other absorbent structure(s) may have varying caliper zones, a hydrophilic gradient, a superabsorbent gradient, or lower average density and lower average basis weight acquisition zones; or may comprise one or more layers or structures).

Exemplary absorbent structures for use as the absorbent assemblies are described in U.S. Patent 4,610,678 entitled "High-Density Absorbent Structures" issued to Weisman et al. on September 9, 1986; U.S. Patent 4,673,402 entitled "Absorbent Articles With Dual-Layered Cores" issued to Weisman et al. on June 16, 1987; U.S. Patent 4,834,735, entitled "High Density Absorbent Members Having Lower Density and Lower Basis Weight Acquisition Zones", issued to Alemany et al. on May 30, 1989; U.S. Patent 4,888,231 entitled "Absorbent Core Having A Dusting Layer" issued to Angstadt on December 19, 1989; U.S. Pat. No. 5,137,537 entitled "Absorbent Structure Containing Individualized, Polycarboxylic Acid Crosslinked Wood Pulp Cellulose Fibers" which issued to Herron et al. on August 11, 1992; U.S. Patent 5,147,345 entitled "High Efficiency Absorbent Articles For Incontinence Management" issued to Young et al. on September 15, 1992; U.S. Pat. No. 5,342,338 entitled "Disposable Absorbent Article For Low-Viscosity Fecal Material" issued to Roe on August 30, 1994; U.S. Pat. No. 5,260,345 entitled "Absorbent Foam Materials For Aqueous Body Fluids and Absorbent Articles Containing Such Materials" issued to DesMarais et al. on November 9, 1993; U.S. Pat. No. 5,387,207 entitled "Thin-Until-Wet Absorbent Foam Materials For Aqueous Body Fluids And Process For Making Same" issued to Dyer et al. on February 7, 1995; and U.S. Pat. No. 5,625,222 entitled "Absorbent Foam Materials For Aqueous Fluids Made From High Internal Phase Emulsions Having Very High Water-To-Oil Ratios" issued to DesMarais et al. on July 22, 1997. Each of these patents is incorporated herein by reference.

The diaper 20 may also comprise at least one elastic waist feature 34 that helps to provide improved fit and containment. The elastic waist feature 34 preferably extends at least longitudinally outwardly from at least one waist edge 62 of the absorbent core 28 and generally forms at least a portion of the end edge 52 of the diaper 20. Disposable

diapers are often constructed so as to have two elastic waist features, one positioned in the first waist region 36 and one positioned in the second waist region 38. Further, while the elastic waist feature 34 or any of its constituent elements may comprise one or more separate elements affixed to the diaper 20, the elastic waist feature 34 may be constructed as an extension of other elements of the diaper 20, such as the backsheet 26, the topsheet 24, or both the backsheet 26 and the topsheet 24.

The elastic waist feature 34 may be constructed in a number of different configurations including those described in U.S. Pat. No. 4,515,595 issued to Kievit et al. on May 7, 1985; U.S. Pat. No. 4,710,189 issued to Lash on December 1, 1987; U.S. Pat. No. 5,151,092 issued to Buell on September 9, 1992; and U.S. Pat. No. 5,221,274 issued to Buell on June 22, 1993. Other suitable waist configurations may include waistcap features such as those described in U.S. Pat. No. 5,026,364 issued to Robertson on June 25, 1991 and U.S. Pat. No. 4,816,025 issued to Foreman on March 28, 1989. All of the above mentioned references are incorporated herein by reference.

The diaper 20 may also include a fastening system 40. The fastening system 40 preferably comprises tape tabs and/or hook and loop fastening components, although any other known fastening means are generally acceptable. Some exemplary fastening systems are disclosed in U.S. Patent 3,848,594 entitled "Tape Fastening System for Disposable Diaper" issued to Buell on November 19, 1974; U.S. Patent B1 4,662,875 entitled "Absorbent Article" issued to Hirotsu et al. on May 5, 1987; U.S. Patent 4,846,815 entitled "Disposable Diaper Having An Improved Fastening Device" issued to Scripps on July 11, 1989; U.S. Patent 4,894,060 entitled "Disposable Diaper With Improved Hook Fastener Portion" issued to Nestegard on January 16, 1990; U.S. Patent 4,946,527 entitled "Pressure-Sensitive Adhesive Fastener And Method of Making Same" issued to Battrell on August 7, 1990; and the herein before referenced U.S. Pat. No. 5,151,092 issued to Buell on September 9, 1992; and U.S. Pat. No. 5,221,274 issued to Buell on June 22, 1993. The fastening system may also provide a means for holding the article in a disposal configuration as disclosed in U.S. Pat. No. 4,963,140 issued to Robertson et al. on October 16, 1990. Each of these patents is incorporated herein by reference. In alternative embodiments, opposing sides of the garment may be seamed or

welded to form a pant. This allows the article to be used as a pull-on type diaper. such as a training pant.

The diaper 20 may also comprise side panels 30. The side panels 30 may be elastic or extensible to provide a more comfortable and contouring fit by initially conformably fitting the diaper 20 to the wearer and sustaining this fit throughout the time of wear well past when the diaper 20 has been loaded with exudates since the elasticized side panels 30 allow the sides of the diaper 20 to expand and contract.

While the diaper 20 preferably has the side panels 30 disposed in the second waist region 38. the diaper 20 may be provided with side panels 30 disposed in the first waist region 36 or in both the first waist region 36 and the second waist region 38. The side panels 30 may be constructed in any suitable configurations. Examples of diapers with elasticized side panels are disclosed in U.S. Patent 4.857,067. entitled "Disposable Diaper Having Shirred Ears" issued to Wood, et al. on August 15, 1989; U.S. Patent 4,381,781 issued to Sciaraffa, et al. on May 3. 1983; U.S. Patent 4,938,753 issued to Van Gompel, et al. on July 3, 1990; the herein before referenced U.S. Pat. No. 5,151,092 issued to Buell on September 9, 1992; and U.S. Pat. No. 5, 221,274 issued to Buell on June 22, 1993; U.S. Patent No. 5,669,897 issued to LaVon, et al. on September 23, 1997 entitled "Absorbent Articles Providing Sustained Dynamic Fit"; U.S. Patent Application Serial No. 08/915,471 entitled "Absorbent Article With Multi-Directional Extensible Side Panels" filed August 20, 1997 in the names of Robles, et al.; each of which is incorporated herein by reference.

The diaper 20 preferably further includes leg cuffs 32 which provide improved containment of liquids and other body exudates. Leg cuffs may also be referred to as leg bands, side flaps, barrier cuffs, or elastic cuffs. U.S. Patent 3,860,003 describes a disposable diaper which provides a contractible leg opening having a side flap and one or more elastic members to provide an elasticized leg cuff (a gasketing cuff). U.S. Patent Nos. 4,808,178 and 4,909,803 issued to Aziz et al. on February 28, 1989 and March 20, 1990, respectively, describe disposable diapers having "stand-up" elasticized flaps (barrier cuffs) which improve the containment of the leg regions. U.S. Pat. Nos. 4,695,278 and 4,795,454 issued to Lawson on September 22, 1987 and to Dragoo on

January 3. 1989. respectively. describe disposable diapers having dual cuffs. including gasketing cuffs and barrier cuffs. In some embodiments. it may be desirable to treat all or a portion of the leg cuffs with a lotion. as described above.

The diaper 20 may also include pockets for receiving and containing waste, spacers which provide voids for waste. barriers for limiting the movement of waste in the article, compartments or voids which accept and contain waste materials deposited in the diaper, and the like. or any combinations thereof. Examples of pockets and spacers for use in absorbent products are described in U.S. Patent 5.514.121 issued to Roe et al. on May 7, 1996, entitled "Diaper Having Expulsive Spacer"; U.S. Patent 5.171.236 issued to Dreier et al on December 15. 1992. entitled "Disposable Absorbent Article Having Core Spacers"; U.S. Patent 5.397,318 issued to Dreier on March 14. 1995. entitled "Absorbent Article Having A Pocket Cuff": U.S. Patent 5.540.671 issued to Dreier on July 30, 1996, entitled "Absorbent Article Having A Pocket Cuff With An Apex"; and PCT Application WO 93/25172 published December 3, 1993, entitled "Spacers For Use In Hygienic Absorbent Articles And Disposable Absorbent Articles Having Such Spacer"; and U.S. Patent 5,306,266, entitled "Flexible Spacers For Use In Disposable Absorbent Articles", issued to Freeland on April 26. 1994. Examples of compartments or voids are disclosed in U.S. Patent 4,968,312, entitled "Disposable Fecal Compartmenting Diaper", issued to Khan on November 6, 1990; U.S. Patent 4,990,147, entitled "Absorbent Article With Elastic Liner For Waste Material Isolation", issued to Freeland on February 5. 1991; U.S. Patent 5.62.840. entitled "Disposable Diapers", issued to Holt et al on November 5, 1991; and U.S. Patent 5,269,755 entitled "Trisection Topsheets For Disposable Absorbent Articles And Disposable Absorbent Articles Having Such Trisection Topsheets", issued to Freeland et al on December 14, 1993. Examples of suitable transverse barriers are described in U.S. Pat. No. 5,554,142 entitled "Absorbent Article Having Multiple Effective Height Transverse Partition" issued September 10, 1996 in the name of Dreier et al.; PCT Patent WO 94/14395 entitled "Absorbent Article Having An Upstanding Transverse Partition" published July 7, 1994 in the name of Freeland, et al.; and U.S. 5.653.703 Absorbent Article Having Angular

Upstanding Transverse Partition, issued Aug. 5, 1997 to Roe, et al. All of the above-cited references are hereby incorporated by reference herein.

Embodiments of the present invention may also include a waste management device 110 such as is shown in Figure 7. The waste management device 110 may include a waste bag 111 to collect feces, urine or both. The waste bag 111 may have an aperture 121 and a flange 112 surrounding the aperture for preferably adhesive attachment to the perianal area of a wearer. Further, the waste management device 110 has been found to be particularly useful and beneficial when used in conjunction with a garment, or diaper, preferably a disposable diaper. One example of an absorbent article, such as the diaper 120 including a waste bag 111 is shown in Figure 8. If associated with a diaper 120 or other garment, the waste bag 111 may be disposed on or joined to any surface of the article. In one embodiment, the waste bag 111 is joined to the topsheet 124 of the diaper 120.

The waste bag 111 is preferably a flexible receptacle for the containment of excreted fecal matter or urine. Thus, the waste bag 111 is preferably liquid impermeable, and yet it may be breathable. Further, the waste bag 111 is designed of sufficient strength to withstand typical wearing conditions, such as sitting.

The waste bag 111 may comprise one or multiple layers. In one embodiment, the waste bag 111 may comprise three layers, preferably one film and two non-woven layers. The layers of the bag material may comprise any material, preferably so that the bag is liquid impervious. In a preferred embodiment of the present invention a laminate may be formed from a non-woven layer and a film.

Suitable film materials for any of the film layers preferably comprise a thermoplastic material. The thermoplastic material can may be vapor pervious or impervious and can be selected from among all types of hot-melt adhesives, polyolefins especially polyethylene, polypropylene, amorphous polyolefins, and the like; material containing meltable components comprising fibres or polymeric binders including natural fibres such as cellulose - wood pulp, cotton, jute, hemp; synthetic fibres such as fibreglass, rayon, polyester, polyolefin, acrylic, polyamid, aramid, polytetrafluroethylene metal, polyimide; binders such as bicomponent high melt/low melt polymer, copolymer

polyester, polyvinyl chloride, polyvinyl acetate/chloride copolymer, copolymer polyamide, materials comprising blends wherein some of the constituent materials are not meltable; air and vapour permeable materials including microporous films such as those described above with respect to the backsheet and monolithic breathable materials such as HYTREL™ available from DuPont and Pebax™ available from ELF Atochem, France.

The waste bag 111 may have any shape or size. Preferred shapes include flat circular type bags, cone shaped bags, truncated cone shaped bags and pyramidal or truncated pyramidal shaped bags and flat T shaped bags. Further, the waste bag 111 may be provided from a unitary piece of material or a number of separate pieces of material which may be identical or different and which may be sealed at their respective peripheries.

The waste bag 111 may also contain absorbent material. The absorbent material may comprise any absorbent material which is capable of absorbing and retaining liquids. The absorbent material may comprise a wide variety of liquid-absorbent materials commonly used in disposable diapers and other absorbent articles. Some examples are described herein with respect to the absorbent core.

The waste bag 111 is provided with an aperture 121 whereby fecal matter or urine is received from the body prior to storage within the bag cavity. The aperture 121 is preferably surrounded by a flange 112 and may be provided in any shape or size, such as circular, oblong, heart shaped and may be symmetrical or asymmetrical, preferably the aperture has an oblong configuration either in the longitudinal or in the transversal direction. The flange may comprise projections designed to fit the perineal, genital and/or coccygeal area of the wearer.

The flange 112 should be made of soft, flexible and malleable material to allow easy placement of the flange 112 to the perianal or uro-genital area. Typical materials include nonwoven materials, wovens, open celled thermoplastic foams, closed-cell thermoplastic foams, composites of open celled foams and stretch nonwoven, and films.

The waste bag 111 preferably further comprises an attachment means to secure the device to the wearer. Such means may comprise straps and or a body-compatible

pressure sensitive adhesive applied to the wearer facing portion of the waste bag 111 or the flange. Any skin-friendly water resistant pressure sensitive adhesive may be used to attach the device to the perianal or uro-genital area of the wearer. such as hydrocolloid adhesives and hydrogel adhesives. Particularly effective adhesives in providing the desired adhesive properties to secure the flange to the skin of the wearer at the sensitive perianal area. while allowing for relatively painless application and removal. are formed from crosslinking polymers with a plastisicer to form a 3-dimensional matrix.

The present invention may also be embodied in and/or on other absorbent or non-absorbent articles such as incontinence briefs. incontinence undergarments, absorbent inserts. diaper holders and liners. colostomy bags for a natural or artificial anus. feminine hygiene devices (which include. but are not limited to panty liners, sanitary napkins. interlabial devices and tampons). wipes. disposable towels. tissues (facial and toilet tissues). articles with which a saliva sample can be taken, such as a tooth brush, lip stick or lip balm, water absorbing articles, oil absorbing articles, spill cleanup bags, desiccant bags, disposable mops, bandages. therapeutic wraps, supports, disposable heating pads and the like. The diagnostic panel can also be located separately from one or more of the types of articles described above, and one or more of the articles described above can be used as a collection device for collecting the bodily fluid(s) of interest, and the bodily fluid thus collected can thereafter be brought into contact with a diagnostic panel. In addition, in some alternative embodiments, swabs, patches, liquid containers, and the like can be used to collect the bodily fluid(s) of interest.

Non-limiting examples of panty liners and sanitary napkins which may be provided with a diagnostic device include those manufactured by The Procter & Gamble Company of Cincinnati, Ohio as: ALWAYS® ALLDAYS® Pantiliners with DriWeave ® manufactured according to U.S. Patents 4,324,246; 4,463,045; and 6,004,893; ALWAYS® Ultrathin Slender Maxi with Wings manufactured according to U.S. Patents 4,342,314, 4.463,045, 4,556,146, B1 4,589,876, 4,687,478, 4,950,264, 5,009,653, 5,267,992, and Re. 32,649; ALWAYS® Regular Maxi; ALWAYS® Ultra Maxi with Wings; ALWAYS® Maxi with Wings; ALWAYS® Ultra Long Maxi with Wings; ALWAYS® Long Super Maxi with Wings; and ALWAYS® Overnight Maxi with

Wings. An example of a panty liner with a diagnostic device is shown in Figs. 9 and 9A. An example of a sanitary napkin with a diagnostic device is shown in Fig. 12.

Non-limiting examples of interlabial devices which may be provided with a diagnostic device are described in U.S. Patents 5,762,644; 5,885,265; 5,891,126; 5,895,381; 5,916,205; 5,951,537; 5,964,689; 5,968,026; Des. 404,814; and Des. 413,669. An example of an interlabial device with a diagnostic device is shown in Figs. 13-17.

Non-limiting examples of tampons which may be provided with a diagnostic device, and applicators therefor, are described in U.S. Patents 4,726,805; 4,846,802; 4,960,417; 5,087,239; 5,279,541; 5,346,468; 5,348,534; 5,531,674; and 5,566,435. In addition, the diagnostic device could also be placed on a digitally insertable tampon. An example of a tampon with a diagnostic device is shown in Fig. 18.

The article 20 preferably also includes at least one indicator or detection device such as a biosensor 60. As used herein, the term "biosensor" includes a component comprising one or more elements being adapted to detect one or more target microorganisms or related biomolecules (e.g., an enzyme sensor, organella sensor, tissue sensor, microorganism sensor, immunosensor or electrochemical sensor). The microorganisms may or may not be pathogenic. The biosensor elements preferably have the capability to provide a signal of said detection to the wearer, caretaker, or an actuator. In certain embodiments, the elements may be biologically reactive, chemically reactive, binding, or they may operate by physical entrapment. The term "biologically reactive" is defined as having the capability to selectively interact with, and preferably bind, target microorganisms and/or related biomolecules as described herein. The term "biologically reactive" includes, but is not limited to elements that detect the presence of enzymes. Generally, biosensors function by providing a means of specifically binding, and therefore detecting, a target biologically active analyte. In this way, the biosensor is highly selective, even when presented with a mixture of many chemical and biological entities, such as feces, menses, sweat, and saliva. Chemical sensors, on the other hand, which rely on chemically reactive means, generally do not have either the high selectivity or the amplification properties of biosensors and, therefore, are not as well suited to

detect biologically reactive analytes, especially when they are present in low concentrations and/or in a complex media such as bodily fluids, bodily waste, and other bodily discharges. Often the target biological analyte is a minor component of a complex mixture comprising a multiplicity of biological and other components. Thus, in many biosensor applications, detection of target analytes to the parts-per-billion, parts-per-trillion, or even lower levels is necessary. Accordingly, discrimination ratios of about 10^7-10^8 or greater may be required for the biosensor to recognize the target biological analyte in a complex mixture.

The biosensor used in the present invention preferably comprises a bio-recognition element, or molecular recognition element, that provides the highly specific binding or detection selectivity for a particular analyte. The bio-recognition element, or system, may be a biologically derived material such as an enzyme or sequence of enzymes; an antibody; a membrane receptor protein; DNA; an organelle, a natural or synthetic cell membrane; an intact or partial viable or nonviable bacterial, plant or animal cell; or a piece of plant or mammalian tissues, and generally functions to interact specifically with a target biological analyte. The bio-recognition element is responsible for the selective recognition of the analyte and the physico-chemical signal that provides the basis for the output signal.

Biosensors may include biocatalytic biosensors, and bioaffinity biosensors. In biocatalytic biosensor embodiments, the bio-recognition element is "biocatalytic" and may comprise an enzyme, organelle, piece of plant or mammalian tissue, or whole cells, the selective binding sites "turn over" (i.e., can be used again during the detection process), resulting in a significant amplification of the input signal. Biocatalytic sensors such as these are generally useful for real-time, continuous sensing.

Bioaffinity sensors are generally applicable to bacteria, viruses, and toxins and include chemoreceptor-based biosensors and/or immunological sensors (i.e. immunosensors). Chemoreceptors are complex biomolecular macroassemblies responsible, in part, for a viable organism's ability to sense chemicals in its environment with high selectivity. Chemoreceptor-based biosensors comprise one or more natural or synthetic chemoreceptors associated with a means to provide a signal (visual, electrical,

etc.) of the presence or concentration of a target biological analyte. In certain embodiments, the chemoreceptor may be associated with an electrode (i.e., an electrical transducer) so as to provide a detectable electrical signal. Chemoreceptors may include whole or partial nerve bundles (e.g., from antennae or other sensing organs) and/or whole or partial natural or synthetic membranes. On the other hand, the bio-recognition elements of immunosensors are generally antibodies. Antibodies are highly specific and can be made toward bacteria, viruses, fragments of microorganisms (e.g., bacterial cell walls, parasite eggs or portions thereof, etc.), and large biomolecules. Suitable antibodies may be monoclonal or polyclonal. In any case, bioaffinity biosensors are generally irreversible because the receptor sites of the biosensor become saturated when exposed to the target biological analyte.

In certain embodiments, biocatalytic bioaffinity biosensors may be combined, such as RNA/DNA probes or other high-affinity binding systems wherein the initial bio-recognition event is followed by biological amplification of the signal. For example, a specific bacteria may be detected by a biosensor comprising genetic material, such as DNA, as a bio-recognition element and PCR (i.e., polymerase chain reaction) amplification to detect small numbers of organisms, preferably less than or equal to about 500. Biocatalytic and bioaffinity biosensor systems are described in more detail in Journal of Chromatography, 510 (1990) 347-354 and in the Kirk-Othmer Encyclopedia of Chemical Technology, 4th ed. (1992), John Wiley & Sons, NY, the disclosure of which is incorporated by reference herein.

The biosensors used in the present invention may detect biologically active analytes related to impending (i.e., future presentation of symptoms is likely) or current human systemic disease states, including, but not limited to, pathogenic bacteria, parasites (e.g., any stage of the life cycle, including eggs or portions thereof, cysts, or mature organisms), viruses, fungi such as Candida albicans, antibodies to pathogens, and/or microbially produced toxins. Additionally, the biosensor may target biologically active analytes related to impending or current localized health issues, such as stress proteins (e.g., cytokines) and IL-1α (interleukin 1-alpha) that may precede the clinical presentation of skin irritation or inflammation. In preferred embodiments, the biosensor

functions as a proactive sensor, detecting and signaling the wearer or caretaker of the impending condition prior to the presentation of clinical symptoms. This allows time to administer prophylactic or remedial treatments to the wearer which can significantly reduce, if not prevent, the severity and duration of the symptoms. Further, the biosensor 60, by detecting the presence of a target biological analyte in the wearer's bodily waste (e.g., feces), may detect residual contamination on a surface, such as skin, in contact with the biosensor, and provide and appropriate signal.

The physico-chemical signal generated by the bio-recognition element or elements may be communicated visually to the wearer or caretaker (i.e., via a color change visible to the human eye as in a colorimetric sensor). Other embodiments may produce optical signals, which may require other instrumentation to enhance the signal. These include flourescence, bioluminesence, total internal reflectance resonance, surface plasmon resonance, Raman methods and other laser-based methods. Exemplary surface plasmon resonance biosensors which may comprise bioconjugate surfaces as bio-recognition elements are available as IBIS I and IBIS II from XanTec Analysensysteme of Muenster, Germany. Alternatively, the signal may be processed via an associated transducer which, for example, may produce an electrical signal (e.g., current, potential, inductance, or impedance) that may be displayed (e.g., on a readout such as an LED or LCD display) or which triggers an audible or tactile (e.g., vibration) signal or which may trigger an actuator, as described herein. The signal may be qualitative (e.g., indicating the presence of the target biological analyte) or quantitative (i.e., a measurement of the amount or concentration of the target biological analyte). In such embodiments, the transducer may optionally produce an optical, thermal or acoustic signal.

In any case, the signal may also be durable (i.e., stable and readable over a length of time typically at least of the same magnitude as the usage life of the article) or transient (i.e., registering a real-time measurement). Additionally, the signal may be transmitted to a remote indicator site (e.g., via a wire, or transmitter, such as an infrared or rf transmitter) including other locations within or on the article or remote devices. Further, the biosensor 60, or any of its components, may be adapted to detect and/or signal only concentrations of the target biological analyte above a predefined threshold

level (e.g., in cases wherein the target biological analyte is normally present in the body substance, or when the concentration of the analyte is below a known "danger" level).

As described above, the target analytes that the biosensors of the present invention are adapted to detect may be pathogenic microorganisms such as the pathogenic microorganisms implicated in human gastrointestinal diseases, especially those resulting in diarrhea. This type of pathogen is particularly important to monitor due to the number of children who become seriously ill or die each year from diarrheal diseases. It has been found that severe chronic diarrhea may result in weight loss and permanent physical and mental developmental retardation. A non-limiting list of pathogenic bacteria that the biosensor 60 may detect include any of the various pathogenic strains of *Escherichia coli* (commonly known as *E. Coli*), including enteropathenogenic *E. coli* (EPEC), enterotoxigenic *E. coli* (ETEC), enterohemorragic *E. coli* (EHEC), enteroinvasive *E. coli* (EIEC), and enteroadherent *E. coli* (EAEC) strains; *Salmonella* strains, including *S. typhi*, *S. paratyphi*, *S. enteriditis*, *S. typhimurium*, and *S. heidelberg*; *Shigella* strains such as *Shigella sonnei*, *Shigella flexneri*, *Shigella boydii*, and *Shigella dysenteriae*; *Vibrio cholerae*; *Mycobacterium tuberculosis*; *Yersinia enterocolitica*; *Aeromonas hydrophila*; *Plesiomonas shigelloides*; *Campylobacter* strains such as *C. jejuni* and *C. coli*; *Bacteroides fragilis*; and *Clostridia* strains, including *C. septicum*, *C. perfringens*, *C. botulinum*, and *C. difficile*. Non-limiting examples of commercially available biosensors adapted to detect *E. coli* are available from AndCare, Inc. of Durham, NC, as test kit #4001 and from Meridian Diagnostics, Inc. of Cincinnati, OH, as *Immuno*Card®STAT! *E. coli* 0157 Plus assay. Another non-limiting example of a commercially available biosensor adapted to detect rotavirus is available from Meridian Diagnostics, Inc. of Cincinnati, OH, as *Immuno*Card®STAT! Rotavirus assay. Another non-limiting example of a commercially available biosensor adapted to detect *Cryptosporidium* and *Giardia lamblia* is available from Meridian Diagnostics, Inc. of Cincinnati, OH, as the Merifluor Crypto/Giardia assay. Another non-limiting example of a commercially available biosensor adapted to detect *C. difficile* toxin is available from Meridian Diagnostics, Inc. of Cincinnati, OH, as the Premier *C. difficile* Toxin A assay. ABTECH, Scientific, Inc., of Yardley, PA offers "bioanalytical biotransducers",

available as BB Au-1050.5-FD-X, which may be rendered biospecific (for microorganisms or other target biological analytes as described herein) by covalently immobilizing polypeptides, enzymes, antibodies, or DNA fragments to their surfaces. Other suitable microbial biosensors, or sensing systems, for one or more of the pathogens of interest are described in US Patents 5,948,694; 6,001,556; 5,106,965 (adenovirus); 5,869,272 (gram negative organisms); 5,795,717 (*Shigella*); 5,830,341; 5,795,453; 5,354,661; 5,783,399; 5,840,488; 5,827,651; 5,723,330; and 5,496,700, all of which are incorporated herein by reference.

The target analytes that the biosensors of the present invention are adapted to detect may also be viruses. These may include diarrhea-inducing viruses such as rotavirus, adenovirus (a dsDNA virus), astrovirus (an RNA virus), calcivirus (an RNA virus), and Norwalk viruses (RNA viruses), or other viruses such as rhinovirus and human immunodeficiency virus (HIV). An exemplary biosensor adapted to detect HIV is described in US Patents 5,830,341 and 5,795,453, referenced above. The disclosure of each of these patents is incorporated by reference herein.

In alternative embodiments, the target analytes that the biosensors of the present invention are adapted to detect may also be parasites, especially those which inhabit the gastrointestinal tract during some point in their life-cycle (e.g., eggs or portions thereof, oocytes, trophozoites, adults). Such parasites may include protozoans, worms, and other gastrointestinal parasites. Other examples of parasites which may be detected include *entamoeba histolytica* (which cause amoebic dysentery), *Cryptosporidium*, *Giardia lamblia*, and *Dientomeba fragilis*, *Trypana cruzi* (which causes Chagas disease), and *Plasmodium falciparum*.

In yet other embodiments, the target analytes the biosensors of the present invention are adapted to detect may be fungi such as *Candida albicans*. In addition to pathogenic bacteria, certain beneficial colonic bacteria may be detected and/or measured as a health indicator, such as *Bifidobacteria* and *Lactobacillus* strains.

The target analytes that the biosensors of the present invention are adapted to detect may also be proteins or antigens related to skin distress. Preferably, these analytes are detectable on or at the skin surface, preferably prior to the presentation of clinically

observable skin irritation. These may include stress proteins such as cytokines, histamine, and other immune response factors including interleukins (such as IL-1α, IL-2, IL-3, IL-4, and IL-8) and interferons (including interferons a and g). Again, these are preferably detectable by the biosensor 60 prior to the onset of clinically observable redness, irritation, or dermatitis. Additionally, the biosensors of the present invention may be adapted to detect enzymes, or other biological factors, implicated in skin irritation (e.g., diaper dermatitis), including tryspin, chymotrypsin, and lipase.

In certain preferred embodiments of the present invention, the article may comprise a diagnostic panel. A "diagnostic panel", as used herein, comprises the combination of two or more biosensors, or other types of indicators, adapted to detect the presence or absence of at least two of a specific group of substances. These substances can be indicators of the physical conditions or state of well being of a mammal, or the cause of a particular disease state, such as diarrhea, vaginal infections, sexually transmitted diseases ("STD's"), and other diseases. The biosensors can, for example, be adapted to detect the presence of at least two of a specific group of pathogens for the purpose of determining the class of pathogens or specific pathogen(s) causing a particular disease state, generally in order to provide a diagnosis leading to a specific course of remedial medical treatment. For example, the article may comprise a diagnostic panel adapted to determine the pathogenic cause, or causes, of diarrhea or vaginal infections. Examples of physical conditions or the state of well being that the diagnostic panel can be adapted to detect include, but are not limited to ovulation and the onset of menstruation. Examples of substances that the diagnostic panel can be adapted to detect in order to determine the onset of menstruation include, but are not limited to: progesterone, pH, and red blood cells (hemoglobin).

In one embodiment of a diagnostic panel particularly suitable for the articles of the present invention, the diagnostic panel may provide an indication to the user of the presence of one of the common viral causes of diarrhea. Such an article provides an indication alerting the user, caregiver, or health professional that the cause of the diarrhea is of viral nature. Such an diagnostic panel may comprise biosensors adapted to detect at least two of the following group of viruses: rotavirus, adenovirus, astrovirus, calcivirus,

and Norwalk viruses. However, it is preferred that the diagnostic panel be capable of detecting the presence of as many of the above viral causes of diarrhea as possible. In any case, the signal to the user, caretaker, or health professional from the diagnostic panel may indicate the specific viral cause of the diarrhea or may merely indicate that the cause is of viral nature.

Alternatively, the article may comprise a diagnostic panel adapted to detect any of the potential bacterial causes of diarrhea or vaginal infections. In certain preferred embodiments, the diagnostic panel may comprise biosensors adapted to detect at least two of the following group of bacteria: EPEC, ETEC, EHEC, EAEC, EIEC, *Campylobacter jejuni*, *Vibrio cholerae*, and *Shigella* strains, including *S. sonnei* and *S. flexneri*. However, it is preferred that the diagnostic panel be capable of detecting the presence of as many of the above bacterial causes of diarrhea or vaginal infections as possible. Preferably, the presence of any of the above bacterial causes of diarrhea or vaginal infections are indicated by the diagnostic panel. In any case, the signal to the user, caretaker, or health professional from the diagnostic panel preferably indicates the specific cause (i.e., bacterial pathogen) of the diarrhea or vaginal infections, allowing the early and specific treatment of the health condition.

Alternatively, the article may comprise a diagnostic panel adapted to detect any of the potential viral and bacterial causes of diarrhea (or vaginal infections). In certain preferred embodiments, the diagnostic panel may comprise one or more biosensors adapted to detect at least one virus and one or more biosensors adapted to detect at least one bacteria. However, it is preferred that the diagnostic panel be capable of detecting the presence of as many of the above bacterial and viral causes of diarrhea (or vaginal infections) as possible. In any case, the signal to the user, caretaker, or health professional from the diagnostic panel preferably indicates the specific cause (i.e., viral or bacterial pathogen) of the diarrhea (or vaginal infections), allowing the early and specific treatment of the health condition.

Alternatively, the article may comprise a diagnostic panel may be adapted to detect specific protozoan causes of diarrhea. In this embodiment, the diagnostic panel may comprise biosensors adapted to detect one or more of the group: *Cryptosporidium*,

Giardia lamblia, *Dientomeba fragilis*, and *Entamoeba histolytica*. Again, it is preferred that the diagnostic panel be capable of detecting the presence of as many of the above protozoan causes of diarrhea as possible. In any case, the signal to the user, caretaker, or health professional preferably indicates the specific protozoan causing the diarrhea, allowing the early and specific treatment of the health condition.

Of course, the diagnostic panel may also be adapted to detect any combination of the pathogenic causes of diarrhea. For example, the diagnostic panel may comprise biosensors adapted to detect two or more of each of the hereinbefore mentioned viral, bacterial, and protozoan causes of diarrhea.

The article may comprise a diagnostic panel that is adapted to detect and signal specific protozoan or pathogenic causes of vaginal infections, similarly to the manner described in the preceding two paragraphs for the case of diarrhea.

A non-limiting embodiment of an exemplary diagnostic panel 10 suitable for incorporation into a disposable diaper is shown in Figures 1B-1E. The diagnostic panel 10 includes two biosensors 12, a biosensor 14 adapted to detect *E. coli* H0157 and a biosensor 16 adapted to detect rotavirus. The diagnostic panel 10 may be made by obtaining biosensors 12 from the hereinbefore mentioned *Immuno*Card®STAT! *E. coli* 0157 Plus and *Immuno*Card®STAT! Rotavirus kits, available from Meridian Diagnostics. The biosensors are removed from their respective "cards" and attached to an exposed surface of a substrate 18 via any attachment or bonding means as known in the art, such as an adhesive. The substrate 18 may comprise any suitable material such as paper, cardboard, a polyolefinic film, etc. In one embodiment, the substrate 18 is a relatively stiff cardboard material. As shown in Figure 1C, a mask 17 having openings corresponding to the biosensors 12 may be applied to the surface of the substrate 18 to ensure fecal contact only with the biosensors 12 themselves and not the remainder of the substrate 18 surface. The substrate 18, or mask 17, may be made of any material such as plastic, cardboard, or paper, and may comprise markings, instructions, or other indicia to aid in performance of the test or the interpretation of the results. For example, the substrate 18 may comprise a color change "key" to assist the user in the correct interpretation of the results. The diagnostic panel 10 is attached to the wearing-facing

surface of the diaper topsheet in the crotch region of the diaper corresponding to the location of the wearer's anus via any attachment or bonding means as known in the art, such as an adhesive. Alternatively, the diagnostic panel may be made by attaching the hereinbefore mentioned *E. coli* 0157 Plus and *Immuno*Card®STAT! Rotavirus biosensor cards directly to the wearing-facing surface of the diaper topsheet in the crotch region of the diaper corresponding to the location of the wearer's anus.

In any of the above embodiments, the diaper topsheet may comprise at least one aperture and the diagnostic panel 10 may be attached to the region of the underlying absorbent core corresponding to the topsheet aperture(s). Regardless of the configuration chosen, the feces contacts the "sample" region of both biosensors 12 upon defecation. The fecal sample may optionally be diluted with a diluent, such as the diluent provided with the *Immuno*Card®STAT! Kit, upon removal of the diaper from the wearer or application of the fecal sample to the biosensors 12. This is especially helpful when the fecal sample is solid. In any event, the results from the biosensors 12 may be read approximately 10 minutes after defecation or, if diluent was added, 10 minutes after the sample dilution. In certain alternate embodiments, the biosensors 12 may be attached to any region of the diaper, such as the topsheet, backsheet, cuffs, and fasteners. In these embodiments, the fecal sample must be applied, after optional dilution, to the test region of both biosensors 12 by the wearer or caregiver upon opening of the diaper or removal of the diaper from the wearer. In any of the above embodiments, the combination of the two biosensors 12 provides a diagnosis for the diarrhea based on common viral (rotavirus) and bacterial (E. coli) causes of diarrhea.

As shown in Figures 1D and 1E, The above diagnostic panel 10 may also comprise an integral wiping mechanism 19 to remove excess feces from the biosensors 12 to facilitate accurate interpretation of the results. The wiping mechanism 19 may comprise a sliding bar including a flexible wiping flap having little or no clearance with the top surface of the biosensor 12 that may be manually slid down the diagnostic panel 10 face to scrape excess feces from the biosensor 12 surface.

Alternatively, the colorimetric biosensor films described and claimed in U.S. Patent 6,001,556 adapted to detect rotavirus and E. coli, and optionally other diarrheal

pathogens as described herein. may be used in place of the Meridian Diagnostic *Immuno*Card®STAT! biosensors in the diaper embodiments described above. These films have the advantage of being thinner and smaller in area than many of the alternative biosensor systems. It should additionally be noted that any of the other biosensors described herein may be substituted or added to the foregoing examples, including both colorimetric and electrochemical biosensors.

The biosensors of the present invention may also comprise bio-recognition systems, including enzymes or binding proteins such as antibodies immobilized onto the surface of physico-chemical transducers. For example, a specific strain of bacteria may be detected via biosensors employing antibodies raised against that bacterial strain. Alternatively, a target bacteria may be detected by a bio-recognition element (including antibodies and synthetic or natural molecular receptors) specific to extracellular products of the target bacteria, such as toxins produced by that strain (e.g., *E. coli*). Exemplary enzyme electrodes that may be used to detect phenols (e.g. in urine or feces) include tyrosinase based electrodes or polyphenol oxidase enzyme electrodes described in U.S. Patent No. 5,676,820 entitled "Remote Electrochemical Sensor," issued to Joseph Wang et al. on October 14, 1997 and U.S. Patent No. 5,091,299 entitled "An Enzyme Electrode For Use In Organic Solvents," issued to Anthony P. F. Turner et al. on February 25, 1992, respectively. Both of these patents are incorporated by reference herein.

In any of the foregoing examples, the specific microorganism may be directly detected or may be detected by binding a toxin, enzyme, or other protein produced by the organism or an antibody, such as a monoclonal antibody, specific to the organism. Exemplary biosensors adapted to detect proteolytic enzymes described in US Patent 5,607,567 and toxins in US Patents 5,496,452; 5,521,101; and 5,567,301.

In a non-limiting embodiment of an exemplary diagnostic panel for vaginal infections, the biosensor may be adapted to detect various specific types of bacteria that may be the cause of bacterial vaginosis, including *Gardnerella vaginalis*, *Prevotella bivia*, *Bacteroides* species, *Mycoplasma hominis*, and *Mobiluncus* species. The biosensor may be adapted to detect non-specific types of bacteria that may be the cause of bacterial vaginosis. The biosensor may also be adapted to detect fungi such as

Candida species, which is the cause of yeast vaginitis (or yeast infections). The biosensor may also be adapted to detect protozoa such as *Trichomonas vaginalis*, which is the cause of Trichomoniasis, a non-reportable sexually transmitted disease, Chlamydia, or other sexually-transmitted diseases. A non-limiting example of a commercially available biosensor adapted to detect *G. vaginalis* is the FEM EXAM® *G. vaginalis* PIP Activity TestCard available from Litmus Concepts, Inc. of Santa Clara, CA. The FEM EXAM® *G. vaginalis* TestCard is described in U.S. Patent 5,571,684. A non-limiting example of a commercially available biosensor adapted to detect non-specific causes of bacterial vaginosis is the FEM EXAM® pH and Amines TestCard available from Litmus Concepts, Inc. The FEM EXAM® pH and Amines TestCard is described in U.S. Patent 5,660,790. Other Litmus Concepts patents and patent publications of interest include: 5,268,146; 5,416,003; 5,585,273; 5,897,834; and PCT Publication WO 94/24306. Non-limiting examples of biosensors adapted to detect Candida and Chlamydia are described in U.S. Patents 5,741,662 and 5,773,234, respectively, issued to Quidel Corporation of San Diego, CA.

In other preferred embodiments, the diagnostic panel may comprise biosensors adapted to detect at least two of the following group of bacteria: various types of bacteria that may be the cause of bacterial vaginosis, including *Gardnerella vaginalis*, *Prevotella bivia*, *Bacteroides* species, *Mycoplasma hominis*, and *Mobiluncus* species.

Fig. 9 shows a non-limiting panty liner embodiment 920 containing an exemplary diagnostic panel 960 for detecting the various causes of vaginitis. The diagnostic panel 960 shown in Fig. 9 contains five sensor elements, 962, 964, 966, 968, and 970. Each of these sensor elements is adapted to detect one or more of the causes of vaginitis alone, or in combination with one or more of the other sensor elements. Sensor element 962 is adapted to detect pH. Sensor element 964 is adapted to detect the presence of amines. Sensor element 966 is adapted to detect *G. vaginalis*. Sensor element 968 is adapted to detect *Candida* species. Sensor element 970 is adapted to detect *Trichomonas vaginalis*. The sensor elements can be of any suitable shape, and in any suitable arrangement, and are not limited to the row of square shaped sensors shown.

The combination of sensor elements 962 and 964 can be used to detect non-specific causes of bacterial vaginosis. An early study of bacterial vaginosis (BV) involved comparisons of the pH of vaginal fluids of women known to be suffering from BV with those known to be free of the disease - Gardner, H.L., et al., *Am. J. Obstet. Gynecol.* 69: 962 (1955). All of the BV positive women in the study were determined to have a vaginal fluid pH greater than 4.5, and 91% of these women had a vaginal fluid pH greater than 5.0. Studies subsequent have now adjusted the pH threshold to 4.7.

In addition to pH, a report by Amsel, R., et al., *Am J. Med.* 74:14-22 (1983) established three other indicators of BV. These are vaginal fluid homogeneity, the whiff test (treatments with alkali followed by an olfactory test to detect for an amine odor), and the presence of clue cells. The presence of two of these indicators (pH and amines) corresponds closely to results obtained when testing for all four indicators of BV.

Preferred pH indicators are bromophenol blue, bromochlorophenol blue, bromocresol green, bromocresol purple, bromothymol blue, brilliant yellow, and nitrazine yellow. A particularly preferred pH indicator is nitrazine yellow which, when in combination with quaternary ammonium groups, changes directly from greenish-yellow to blue over a narrow pH range of approximately 0.1 pH units as the pH rises, the transition centering around pH 4.7.

The quaternary ammonium groups can be any groups capable of asserting a positive charge sufficient to form an ionic attraction with the negatively charged group(s) in the indicator. Preferred quaternary ammonium groups are lower alkyl ammonium groups in which the alkyl groups are C_1 - C_4 alkyl groups. Trimethylammonium groups are particularly preferred.

The whiff test, which is one of the Amsel criteria, originated in a study by Pheifer, et al., *N. Engl. J. Med.* 298: 1429-1434 (1978), that reported the presence of a characteristic fishy amine odor upon the addition of 10% KOH to a vaginal fluid specimen from a woman with BV. The odor is caused by the alkaline volatilization of amine salts found in the vaginal fluid of women with BV.

The amine test differentiates between amines volatilized by alkali and those that are not volatilized by alkali by incorporating solid alkali accessible to the specimen, an

indicator accessible to a liquid specimen, and an indicator accessible only to vapors emitted by the specimen, in the same device. Thus, the specimen is first contacted with the solid alkali, then applied to both indicators, one of which sill undergo a color change regardless of the presence or absence of volatile amines, and the other a color change only in the presence of volatile amines.

The choice of solid alkali for the gas-releasing lamina is not critical and can vary. In general, alkali and alkaline earth metal aluminates, carbonates and hydroxides can be used. Best results will most often be achieved with the use of either sodium aluminate, sodium carbonate, or magnesium hydroxide. Sodium aluminate is particularly preferred.

Any indicator that changes color upon exposure to amines, and preferably amines in a fluid specimen that would otherwise be acidic, may be used. Bromocresol green is one example, and may be used here as well as in the pH test. Other examples are bromophenol blue, bromocresol purple, bromochlorophenol blue, nitrazine yellow, and various other indicators.

Sensor elements 962 and 964 can comprise the hereinbefore mentioned FEM EXAM® pH and Amines TestCard sensors available from Litmus Concepts, Inc. to detect non-specific causes of bacterial vaginosis, which use technology described in U.S. Patent 5,910,447.

Sensor element 966 is adapted to detect *G. vaginalis*. In 1988, a report by Thomason, et al. (*Obstet. Gynecol.*,71(4): 607 (1988)) suggested that bacterial enzyme activity, specifically proline iminopeptidase activity, in vaginal fluid may be a suitable marker for BV. Proline iminopeptidase serves as a hydrolase. The term "hydrolase" is used herein to refer to a catalyst that is capable of splitting a compound into fragments through the addition of water.

The assay is performed by contacting the sample with a solid-phase conjugate which is susceptible to cleavage by the hydrolase, and either during or subsequent thereto, contacting the sample with an indicator which undergoes a detectable change upon the action of a reporter group which is a portion of the conjugate and is liberated from it either partly or entirely by the action of the hydrolase.

The term "conjugate" is used herein to refer to a reporter group coupled to a substrate residue yet capable of cleavage or decoupling therefrom upon contact with the catalytically active hydrolase whose presence is being detected. The term "reporter group" or (interchangeably) "marker group" is used herein to refer to a moiety which can be hydrolytically released from the substrate residue by a hydrolase and which, in its free form, can react with an indicator to produce a detectable change. Such reporter groups include, but are not limited to, the following: phenols, naphthols, aromatic amines, amino acids, their derivatives and analogs. In a particularly preferred embodiment, naphthylamine, its derivatives or analogs are used as the reporter group.

If the hydrolase of interest hydrolyzes the conjugate at any other point other than freeing the reporter group, the hydrolase by itself would be incapable of releasing the reporter group in active form. One or more assisting hydrolases which could only act in conjunction with the hydrolase of interest could then be incorporated into the assay to complete the release of the reporter group in active form. The assisting hydrolase or hydrolases must therefore be ones which are incapable of releasing the reporter group directly from the intact conjugate, but instead capable of releasing the reporter group only from the cleavage product generated by the hydrolase of interest. The following is an example of the reaction sequence used.

First, the hydrolase of interest, unable to release the reporter group directly, specifically hydrolyzes one or more bonds in the conjugate, thereby releasing a molecular fragment containing the inactive reporter group.

Next, the assisting hydrolase (or hydrolases) releases the reporter group by hydrolyzing the bond between the substrate residue fragment and the reporter group in one or more steps.

The net effect of the foregoing reaction sequence is the release of the reporter group only when the hydrolase of interest is present in the sample.

To illustrate an implementation of the present invention for detecting proline iminopeptidase activity, the sample is placed in a device which contains first and second solid supports, the first solid support being a Mylar® polyethylene laminate on which an L-prolyl-beta-naphthylamide, L-prolyl-beta-methoxynaphthylamide of hydroxy-L-

prolyl-beta-naphthylamide conjugate is deposited. the second solid support being a Mylar® polyethylene laminate on which Fast Garnet GBC. a chromogenic indicator which undergoes a detectable change upon action of beta-naphthylamine. is deposited. The sample is placed in the device in such a manner that the sample contacts the first and second solid supports such that any beta-naphthylamine released by proline iminopeptidase activity in the sample is permitted to diffuse through the sample to the second solid support. The Fast Garnet GBC is then observed for a detectable change as an indication of the presence of the enzyme in the sample. The conjugate may be incorporated in a matrix of water-soluble polymer such as hydroxypropyl cellulose. The Fast Garnet GBC indicator may be incorporated in a water-insoluble matrix of ethylcellulose which contains a penetrant such as manganese chloride.

Sensor element 966 can comprise the hereinbefore mentioned FEM EXAM® *G. vaginalis* PIP Activity TestCard available from Litmus Concepts, Inc., which uses technology described in U.S. Patent 5,571,684.

Sensor element 968 is adapted to detect *Candida* species. It is known that enzymatically active *Candida albicans* aspartic protease is present in the vaginal fluid of women with vulvovaginal candidiasis. It is further known that the presence of enzymatically active aspartic protease in a sample or specimen can serve as a marker for the detection and diagnosis of candidiasis. Therefore, a method was developed for detecting candidiasis by assaying for the presence of enzymatically active aspartic protease in a sample.

In this method, a sample, e.g., vaginal fluid, is contacted with a solid support. The solid support with which the sample is contacted has a reporter enzyme (i.e., a signal generating enzyme) immobilized thereon. The reporter enzyme is immobilized on the solid support in a manner such that it is released from the solid support upon action of the enzymatically active aspartic protease if the enzymatically active aspartic protease is, in fact, present in the sample. The sample after having been contacted with the solid support is combined with an indicator. The indicator is any chemical species which is susceptible to a visible or detectable change (such as, for example. a change in color) upon action of the reporter enzyme. If after contact with the sample the indicator

undergoes a detectable change. enzymatically active aspartic protease is present in the sample and. hence. it can be said that candidiasis is present.

The term "reporter enzyme" or (interchangeably) "marker enzyme" is used herein to refer to a signal generating enzyme. i.e., an enzyme whose activity brings about a detectable change. Such reporter enzymes include. but are not limited to. the following: peroxidases. phosphatases. oxidoreductases. dehydrogenases. transferases. isomerases, kinases, reductases. deaminases. catalases. urease. and glucuronidase. Preferred reporter enzymes are the peroxidases. such as. for example. horseradish peroxidase.

The reporter enzyme is immobilized on a solid support, i.e., an insoluble polymeric material. inorganic or organic matrix. gel. aggregate. precipitate or resin, in such a manner whereby the reporter enzyme is released upon action of the hydrolase whose presence is being assayed. Preferred solid supports include, but are not limited to, the following: cellulose, agarose, dextran, polyacrylate, polyacrylamide, or their derivatives, chitin, sepharose, oxirane acrylic beads and polymeric dialdehyde, starch, collagen, keratin, elastin, bovine hide powder, bacterial cell wall peptidoglycan or fragments thereof, nylon, polyethylene terephthalates, polycarbonates, and controlled pore glass. Immobilization of the reporter enzyme on the solid support is carried out using conventional methods and procedures known to and understood by those skilled in the art.

The term "indicator" used herein in reference to the method for detecting *Candida* species refers to any chemical species which undergoes a detectable change as a result of the reaction or as a result of the culmination of reactions occurring when the enzymatically active hydrolase is present in the sample or specimen. The resulting detectable change is an indication that the enzymatically active hydrolase is present in the sample or specimen. Alternatively, other detection systems may be set up with other appropriate enzymes as analytes and reporter enzymes.

Preferred indicators are visual indicators and, in particular, chromogenic indicators, i.e., those in which the visible change is a change in color, including the formation of color in an otherwise colorless material, upon action of the reporter or marker enzyme when it is released from the solid support by the enzymatically active

hydrolase whose presence is being detected. Alternatively, the reporter enzyme may be capable of catalyzing the formation of a fluorescent signal, a phosphorescent signal, a bioluminescent signal, a chemiluminescent signal, or an electrochemical signal upon its release from the solid support by the action of the hydrolase. Additionally, the reporter enzyme may be capable of producing other visible or detectable signals, such as, for example, a clot, an agglutination, a precipitation, or a clearing zone.

A wide variety of chromogenic indicators (i.e., chromogens) and other species having a similar effect may be used as visual indicators with horseradish peroxidase as the reporter enzyme. Preferred chromogenic indicators comprise a hydroperoxide and a chromogen including, but not limited to, one of the following: guaiac, 2-2'-azino-bis(3-ethyl-benthiazoline-6-sulfonic acid), tetramethylbenzidine, phenol, 4-aminoantipyrine, and 4, 5-dihydroxynaphthatlene-2, 7-disulfonic acid. A particularly preferred chromogenic indicator is comprised of a hydroperoxide and guaiac, a chromogen which is colorless in its reduced state and deep blue in its oxidized state.

Sensor element 968 can utilize the technology described in U.S. Patent 5,416,003.

Sensor element 970 is adapted to detect *Trichomonas vaginalis*. A method is provided for detecting *Trichomonas vaginalis* by assaying for the presence of enzymatically active thiol protease in a sample, this method comprising: (a) contacting the sample with a solid support, the solid support having a reporter enzyme immobilized thereon in such a manner whereby the reporter enzyme is released upon action of the enzymatically active thiol protease; (b) combining the sample after having been contacted with the solid support with an indicator, the indicator being one which is susceptible to a detectable change upon action of the reporter enzyme; and (c) observing whether the indicator undergoes a detectable change, the detectable change being an indication of the presence of enzymatically active thiol protease in the sample and thus, *Trichomonas vaginalis*.

Optionally, one or more of the sensor elements, 962, 964, 966, 968, and 970 can be replaced by a sensor to detect pregnancy. Such a sensor can utilize chromatographic strips. For example, in 1988 a new over-the-counter pregnancy test (Clearblue Easy), developed and patented by Unipath, was introduced. The test uses dyed microspheres in

a sandwich format to give a one step test. To prepare the test, small dark-blue dyed microspheres (Ↄ) are first coated with antibody (Ab_1) to HCG (human chorionic gonadotropin); the microspheres (Ↄ-Ab_1) are dried on one part of a nitrocellulose strip; a second antibody (Ab_2) to HCG is immobilized on another section of the strip.

In use the strip is wetted at one end with urine. As the urine moves by capillary action, it picks up the blue microspheres (Ↄ-Ab_1), and carries them downstream: any HCG in the urine reacts with Ab_1 on the microspheres (Ↄ-Ab_1- HCG). When the flow reaches the immobilized Ab_2-1, the dyed microspheres with HCG (Ↄ-Ab_1- HCG) are captured by Ab_2-1 to form a blue line caused by the HCG sandwich (Ↄ-Ab_1- HCG- Ab_2-1). The blue line signals a positive pregnancy test. Further downstream there is another line of immobilized protein (Ab_3-1) which catches unconjugated Ↄ-Ab_1 as (Ↄ-Ab_1-Ab_3-1) (independent of HCG) to form another blue line which acts as a positive procedural control. If the second line does *not* form, the test results are invalid.

There are also home tests for LH (luteinizing hormone) and similar clinical tests for Strep A, and Chlamydia. Other companies make laboratory single-analyte tests using this chromatographic principle for HCG, common infectious diseases, and DAU (drugs of abuse in urine).

Carter-Wallace's home pregnancy test, First Response®, uses plain microspheres (~1μm) coated with one antibody to hCG and very small (<50nm) red gold sol particles coated with antibody to another hCG epitope. On mixing with a sample of urine, if the sample contains hCG, the particles are coagglutinated, yielding red clumps. The mixture is poured through a filter which catches the red clumps to yield a pink colored filter. With negative urine, unagglutinated red particles pass through the filter and no color develops on it.

Another immunoassay method comprises applying an aqueous solution containing the analyte antigen to one end of a multi-zoned test strip device such that the solution moves along the strip by capillary action. The zones are arranged so that the solution (a) first contacts and reconstitutes dry, diffusible labeled component comprising colloidal gold conjugated to an antibody specific for said analyte antigen and then (b) contacts and reconstitutes dry, diffusible biotinylated second antibody specific for said

analyte antigen such that a diffusible, dispersed sandwich reaction product forms. The reaction product diffuses along the strip with the solution and into a zone containing capture component consisting of a latex and avidin complex which avidin collects the reaction product by means of reaction with its biotin moiety. Thus, gold particles are collected and concentrated in the detection zone for visual determination.

Technologies which allow multiple analyte assays are also of potential use in this invention. These include, but are not limited to, antibody labeled microbeads, Silas (TR) surface analysis, or membrane based biosensors.

In practice, an array of sensors may be placed on a surface to be brought into contact with a suitable sample. Samples include, but are not limited to urine, saliva, sweat, and vaginal discharge. The individual sensors respond to their respective analytes and produce a detectable signal. This may be as simple as a color or refractive index change, or may involve a change in an electrical signal such as due to current flow through a biosensor membrane.

For example, antibodies to the appropriate hormones may be immobilized on the surface of the Silas optical wafers by methods known in the art. These wafers may then be separated and arranged in a known pattern on a detection article, for example, a panty liner. Similarly, these antibodies could be immobilized on microbeads and arranged in a lateral flow assay device suitable for urine or saliva matrices. Again, multiple reagents can be used in an array giving readout of all analytes simultaneously.

Simularly, other analytes may be detected in combination with hormones. These include biomarkers for other conditions of interest, such as infections, osteoporosis, etc. SILAS™ or SILICON Assay Surface Technology developed by Biostar, Inc. Of Boulder, Colorado is a proven method for the detection of specific target molecules. Biostar patents on this technology include U.S. Patents 5,955,377; 5,869,272; 5,639,671; 5,629,214; 5,541,057; 5,482,830; 5,468,606; 5,418,136. This thin film based technology has successfully been used for the development of diagnostic tests to detect bacterial and viral antigens from Group A Streptococcus, Group B Streptococcus, Chlamydia, and Influenza A and B (Optical Immunoassay (OIA®)).

The wafer consists of a silicon support with an optical coating and attachment layer. This wafer surface technology enables the direct visual detection of a physical change in the optical thickness of molecular thin films. This change in thickness is due to the specific capture of an analyte on the surface. When substrate is added. this binding event is amplified and again increases the surface thickness of the molecular thin film. This change in thickness alters the reflected light path and is visually perceived as a color change. Slight changes in optical thickness produce a distinct visible color change. A positive result appears as a purple spot on the predominant gold background. When target is not present in the sample, no binding takes place. Therefore, the optical thickness remains unchanged and the surface retains the original gold color indicating a negative result.

Thus, in a first aspect, SILAS™ technology is used in a device for detecting the amount or presence of an analyte of interest. The device includes a substrate which has an optically active surface exhibiting a first color in response to light impinging thereon. This first color is defined as a spectral distribution of the emanating light. The substrate also exhibits a second color which is different from the first color (by having combination of wavelengths of light which differ from that combination present in the first color, or having a different spectral distribution, or by having an intensity of one or more of those wavelengths different from those present in the first color). The second color is exhibited in response to the same light when the analyte is present on the surface.

An "optically active surface" is a surface that participates in the generation of an optical effect such that the light impinging upon that surface is in some way altered. Such optically active surfaces may be adapted to respond not only to polychromatic light (e.g., white light) but also to mono-chromatic light (e.g., laser light, which may be inherently polarized). This technology preferably produce a color signal that strongly contrasts the background interference color of the unreacted test surface and a reacted surface.

Specifically, this technology uses similar devices in which the substrate has an attachment layer formed from a chemical selected from the group consisting of dendrimers, star polymers, molecular self-assembling polymers, polymeric siloxanes,

and film forming latexes; the substrate itself is formed from a material selected from the group consisting of monocrystalline silicon. a amorphous silicon on glass. amorphous silicon on plastic, a ceramic, polycrystalline silicon. and composites of these materials; and the substrate may have an optical thin film formed from a material selected from the group consisting of silicon nitride. silicon/silicon dioxide composites. titanates, diamond, oxides of zirconium, and silicon carbide.

The substrate is selected from the group consisting of glass. and plastic, comprising a layer of amorphous silicon on its surface, whereby an optically active surface is produced; the optically active surface includes monocrystalline silicon or metal; the substrate is metal further having a layer of amorphous silicon; a receptor layer receptive to analyte is provided with a specific binding partner for the analyte; the receptor layer is formed from material selected from the group consisting of antigens, antibodies, oligonucleotides, chelators, enzymes, bacteria, bacterial pili, bacterial flagellar materials, nucleic acids, polysaccharides, lipids, proteins, carbohydrates, metals, viruses, hormones, and receptors for said materials; and the first color is golden in appearance and the second color is purple or blue in appearance to the eye.

In another related aspect, this technology relates to a method for detecting an analyte of interest in a sample, by the steps of providing a thin film optical immunoassay device having a substrate, having an upper and a lower surface, and supporting on its upper surface, an unlabeled antibody layer bound to the substrate, at least one layer containing the analyte from the sample, the analyte containing layer supporting at least one layer having an enzyme conjugate complexed with the analyte; contacting the enzyme conjugate with a precipitating agent; incubating for a time period sufficient to cause precipitation of product from interaction of the precipitating agent and the enzyme; and optically measuring the mass change of the enzyme conjugate layer and the unlabeled antibody layer as an indication of the amount of the analyte in the test sample.

Preferably, the enzyme conjugate has an immobilized peroxidase or an anti-bacterial anti-body-horseradish peroxidase complex; or the enzyme conjugate is alkaline phosphatase and comprises an anti-bacterial -antibody- alkaline phosphatase complex; and the precipitating agent is a substrate containing 5-bromo-4chloro-3indolyl phosphate.

The panty liner 920 shown in Fig. 9 comprises a hybrid topsheet. comprising an apertured film with a non woven material in the form of strips joined to the apertured film along the sides of the pantiliner as described in U.S. Patent 6.004.893. Van Tilburg. The components of the topsheet can be joined in any suitable manner. such as in the manner shown in Fig. 9 (by a plurality of circular fusion binds arranged in a sinusoidal pattern).

The sensor elements 962. 964, 966. 968. and 970 can be attached to the wearing-facing surface of the panty liner topsheet 924. The sensors can be attached in the region of the panty liner corresponding to the location of the wearer's vagina. The sensors can be attached via any attachment or bonding means as known in the art, such as an adhesive. Alternatively. the topsheet 924 may comprise at least one aperture and the sensors may be attached to the region of the underlying absorbent core corresponding to the topsheet aperture(s).

The sensor elements may be in the nature of a plus or minus sign to indicate the presence or absence of the test analytes in a quantity above a certain threshold as shown in Figs. 9 and 9A. Alternatively, the sensor element may be adapted to provide a colorimetric indication of the quantity of test analytes as shown in the diagnostic panel in Fig. 10, and the darkness of the color on the sensor elements can be compared with a comparison chart 1090, such as that shown in Fig. 11, which indicates the level of test analytes present. The comparison chart can be provided in a number of suitable formats, including, but not limited to, in the form of a card that is packaged with the article on which the sensors are located, or on the outside of the package.

The sensor elements can be covered by a covering 980 to prevent the test reagents in the sensors from coming in contact with the wearer's body, if test reagents are present. Preferably, the covering 980 is clear and also flexible, so that it will not interfere with wearing the article, if the article is of a type to be worn adjacent to a wearer's body. The covering 980 can be made of any suitable material, such as plastic. SARAN® wrap, MYLAR®, or the like. The covering 980 can be apertured to allow body fluids to come into contact with the sensors, or it may be unapertured.

If a covering 980 is used, it may be desirable to provide a fluid transport element, such as a wicking strip 982, underneath and/or on the sides of the sensors to bring the bodily fluids of interest into contact with the sensors.

Fig. 12 shows a non-limiting sanitary napkin embodiment 1220 containing an exemplary diagnostic panel 1260. The sanitary napkin 1220 shown in Fig. 12 also has a plurality of circular fusion bonds arranged in a quilted pattern on its body-facing surface. The sanitary napkin 1220 also has flaps or wings with corrugations therein. However, it should be understood that the present invention can be provided on sanitary napkins having many other suitable configurations.

Figs. 13-15 show a non-limiting interlabial device embodiment 1320 containing an exemplary diagnostic panel 1360. The interlabial device 1320 comprises a topsheet 1342, a backsheet 1338 joined to the topsheet, and an absorbent core 1344 positioned between the topsheet 1342 and backsheet 1338. This embodiment of an interlabial device also includes a handle 1352 to provide the user with a way to grip the device for insertion, and, if desired, removal. As in the case of the other articles shown in the drawings, such a device can be in a wide variety of suitable configurations. Fig. 16 shows how the interlabial device 1320 may be held by a user for insertion into the space between the wearer's labia. Fig. 17 shows the interlabial device in place relative to the wearer's body.

The portions of the wearer's body, W, shown in Fig. 17 are designated as follows: bladder, B, clitoris, C, urethra, U, labia minora, N, labia majora, J, vagina, V, vaginal introitus, VI, anus, A, hymenal ring, H, and large intestine, I. The interlabial device 1320 is inserted so that it is worn between the wearer's labia minora N and labia majora J and blocks the wearer's vaginal introitus VI without entering the vagina past the hymenal ring H. That is, the interlabial device 1320 lies at least partially in the vestibule bounded by the labia minora when such device is worn. Ideally, the interlabial device 1320 is maintained in contact with as large a portion of the inner surface area of the wearer's labia minora N and labia majora J as possible. This will ensure that the interlabial device 1320 intercepts as much of the wearer's body exudates as possible.

In the particular embodiment shown, the interlabial device 1320 is preferably at least partially retained in place by virtue of the folded configuration causing the interlabial device to exert a slight laterally outwardly-oriented pressure on the inner surfaces of the wearer's labia minora, labia majora, or both. Additionally, the product is also held by attraction of naturally moist labial surfaces to the topsheet 1342. Optionally, the topsheet 1342 may be provided with a bio-compatible adhesive to assist the adhesion of the topsheet 1342 to the inside surfaces of the wearer's labia.

In addition, in other embodiments, rather than having a single detector, or diagnostic panel 1360 comprising multiple detectors, located centrally on the topsheet 1342 as shown in Figs. 13-16, the interlabial device 1320 can be provided with detectors that are in numerous other arrangements. In one non-limiting example, the interlabial device 1320 may have spaced apart detectors or diagnostic panels. For example, the interlabial device may be provided with two detectors. One detector may be located toward the front of the interlabial device (for example, to detect causes of adult incontinence or urinary tract infections), and one may be located toward the rear of the device (for example, to detect vaginal infections). The possibility of locating multiple detectors in various different locations also applies to the other types of absorbent articles described herein. However, in the case of interlabial devices, such an arrangement is believed to be particularly beneficial due to the proximity of the interlabial device with the wearer's urethra and vaginal introitus in use. This proximity makes it more likely that the body substance of concern will contact the proper detector.

In other embodiments, interlabial devices with more than one type or location of detection device could be sold together as a kit to detect more than one condition. In still other embodiments, more than one of the types of articles described herein could be sold together in the form of a kit to detect more than one condition.

Fig. 18 shows a non-limiting tampon embodiment 1820 containing an exemplary diagnostic panel 1860.

The biosensor(s) 60 used in the present invention may comprise one or more "proactive sensors". This is especially useful in embodiments where the detection of the target biologically reactive analyte precedes the onset of clinically observable health

symptoms. As used in this application. the term "proactive sensor" refers to a sensor that is capable of detecting changes or signals on the body of the wearer (i.e., skin) or in the body substance, i.e., inputs. that directly relate or. at a minimum. correlate to the occurrence of an impending or potential health or skin related even. Proactive sensors may respond to one or more specific inputs as described above. (It is understood that all of the discussions relating to "biosensor(s) 60" may also apply to the other sensors shown on the articles in the drawings. such as those in diagnostic panels 960. 1260, 1360, and 1860.)

A proactive sensor 60 may detect an impending event or detect a parameter that directly relates. or at a minimum correlates to the occurrence of an impending event, particularly a systemic or skin health event or condition (i.e., the presentation of clinically observable indications or symptoms). An impending event that may be detected or predicted by a proactive sensor 60 of the present invention may include diarrheal disease, skin irritation or rash (including candidiasis), and/or other types of illness or medical conditions of the wearer such as a parasitic infestation. The detected biological analyte may be one or more steps removed from the actual presentation of clinical symptoms. For example, the biosensor may detect potential precursors to the above conditions (e.g., fecal contamination of the skin that may precede the elicitation of stress proteins which may, in turn, precede clinically observable skin irritation. A parameter that correlates to an event is any measurable input, signal such as one or more of the potential inputs listed above, that correlates with the occurrence of the event within the frame of reference of the system (i.e., a signal caused by the waste or the wearer). Proactive sensors 60 in an article may measure one or more different inputs in order to predict an event. For example, the proactive sensor 60 may monitor for *Candida albicans* in the feces and residual colonic bacteria on the skin (i.e., detecting residual contamination) both of which are signals that may precede skin irritation.

In biosensor embodiments wherein the bio-recognition element does not produce an easily visible signal (e.g., a color change). the biosensor 60 may include a transducer in communication with the bio-recognition element in order to convert the physico chemical signal from the bio-recognition element into a usable signal to the wearer,

caretaker, or component of the article (e.g., and actuator). Exemplary transducers may include electrochemical transducers (including potentiometric, amperometric, and conductimetric transducers), optical transducers (including flourescence, bioluminesence, total internal reflective resonance, and surface plasmon resonance), thermal transducers, and acoustic transducers, as known in the art. A power source, such as a miniature 3 volt watch battery or printed thin film lithium battery, may be connected with the biosensor 60 to provide any required power.

The effectiveness of the biosensors of the present invention may be measured with the Response Factor Test described in the Test Method section below. The Response Factor describes the ratio of the response of the biosensor when exposed to fecal test material compared to the response of the biosensor when exposed to physiological saline solution and is useful in assessing the sensitivity of the biosensor for biologically active analytes expected to be found preferentially in feces versus urine. The biosensors of the present invention preferably have a response factor of at least 2, 3, or 5, more preferably at least 10, and even more preferably at least 20 when exposed to fecal test material in aqueous solution or test urine having a concentration of 1 gram of fecal test material per 1 gram of physiological saline solution. (Physiological saline solution is used here to represent the background input signal which is present in most natural environments such as aqueous body fluids.) Such biosensors are able to clearly distinguish between the presence of fecal material and the presence of physiological saline solution with respect to a target biologically active analyte specific to feces.

One way to detect feces is to detect skatole, a substance commonly found in fecal material. It has been found that the skatole concentration in feces is about 180 microgram per gram of fecal material whereas the skatole level in urine has been found to be substantially lower. Skatole is generally a product of microbiological degradation that originates from the catabolism of tryptophane in the intestinal system.

In one preferred embodiment of a skatole detecting biosensor, the biosensor comprises genetically engineered microorganisms which assimilate skatole and or other substances. The assimilation of skatole specific substances can be measured, for example, via the oxygen consumption during the assimilation process. Microorganisms

suitable for detecting skatole include *Acinetobacter baumannii* TOI36 (FERM P-12891. Japanese patent publication JP05304947). and *Bacillus sp* TOI41(FREM P-12914. disclosed in Japanese patent publication JP05304948). Suitable biosensors including such microorganisms are commercially available for example from Institut für Chemo- und Biosensorik of Münster. Germany. under the designation Mikrobielle Sensoren.

If microorganisms are incorporated into a biosensor. they may be immobilized in the biosensor by techniques known in the art such as entrapment. adsorption. crosslinking. encapsulation. covalent attachment. any combination thereof. or the like. Further, the immobilization can be carried out on many different substrates such as known the art. In certain preferred embodiments. the immobilization substrate may be selected from the group of polymer based materials. hydrogels. tissues. nonwoven materials. woven materials. and silicon semi-conductors.

In certain embodiments, the sensor 60, including any biosensor embodiments, may comprise, be disposed on, or be operatively associated with a microchip, such as a silicon chip, MEMs (i.e., micro electromechanical system) device, or an integrated circuit. Microchip-based biosensors may be known as "biochips". Regardless of the type of sensor, the microchip may comprise a multiplicity of sensor components having similar or different sensitivities, kinetics, and/or target analytes (i.e., markers) in an array adapted to detect differing levels or combinations of said analyte(s). Further, each sensor in such an array may provide a different type of signal, including those types disclosed herein, and may be associated with different actuators and/or controllers. Also, each sensor in an array may operate independently or in association with (e.g., in parallel, combination, or series) any number of other sensors in the array.

The biosensor 60 may be disposed in and/or operatively connected to any portion of a disposable article (e.g., diaper 20 of Fig.1), that will be exposed to the input that the biosensor is designed to detect. (It should also be understood that the entire discussion relating to biosensors also applies to the other articles shown in the drawing(s) even though reference number 20 is primarily used to refer to the article in this description.) For the purposes of the present invention. the term "operatively connected" refers to a means of communication such that the biosensor 60 may signal some portion of the

article 20 when the biosensor 60 detects an input. The biosensor 60 may be separate from and operatively connected to another portion of the biosensor 60. another biosensor 60, an actuator. a controller or some other portion or component of the article 20. "Operatively connected" may. for example. include a means of communication such as an electrical connection via a conductive wire or member, via a transmitted signal such as radio frequency. infrared or another transmitted frequency communication. Alternatively. the biosensor 60 may be operatively connected via a mechanical connection such as a pneumatic or a hydraulic connection.

In the diaper shown if Fig. 1. the biosensor 60 may be located in the front waist region 36. the rear waist region 38 or the crotch region 37 of article 20. and may be integral with. disposed adjacent to. joined to. or comprise a portion of the chassis 22. the topsheet 24. the backsheet 26. the absorbent core 28. side panels 30. leg cuffs 32. a waist feature 34, a fastening system 40, the longitudinal 50 or end 52 edges, etc. In certain preferred embodiments wherein the target biological analyte is associated with bodily waste, the biosensor 60 may be disposed in the crotch region of the article 20 so as to maximize the probability of the bodily waste contacting the biosensor 60. In other preferred embodiments wherein the biosensor is adapted to detect or measure a target biological agent on the wearer's skin, the biosensor 60 may be disposed on the topsheet, cuff, a waist feature, a feces receiving pocket, spacer, or any other portion of the article that will contact the wearer's skin during the usage process. In certain embodiments, the biosensor may also be associated with the lotion or other skin care composition within the article.

The biosensor 60 may be integral with the article 20, or may be installed by the caretaker or the wearer. The biosensor during the course of wearing the article, may also become at least partially detached from the article and may be adhered to the wearer's skin. The biosensor may be affixed, permanently or detachably (e.g., via a mechanical fastening system like Velcro™ or a water soluble adhesive) to a support structure, including adhesive tapes, cellulosic or synthetic webs, nonwoven highlofts, films. scrims, foams, and the like. Further, the biosensor 60 may be completely contained within the article such as article 20 or may have a receiving portion located in the article such that it

will come into contact with the desired input and another portion such as a transmitting portion located either in the article or outside the article. The biosensor 60 may be external to the article 20 yet operatively connected to some portion of the article 20 such that the biosensor 60 may detect an input external to the article 20 and provide a signal to a controller and/or an actuator. In some embodiments, the biosensor may be separate from the article, e.g., separately applied to some portion of the wearer via adhesive or other means as known in the art, and/or may have one or more components separate from the article.

In some embodiments, a wiping means or element may be provided to allow the wearer or caretaker to clean sufficient bodily waste from the biosensor 60 to allow a visual assessment or reading of the signal (especially for biosensor embodiments that provide such a signal). The wiping element may include a web (cellulosic or synthetic), nonwoven highloft, film, foam, rigid or semi-rigid squeegee like element, and the like disposed in the article and adapted such that the element may be used to clean the biosensor display. The wiping element may be at least partially affixed the to a component of the article, such as a topsheet, in proximity to the biosensor 60 by any known means in the art. The wiping means may optionally comprise water or any other known cleaning aid to facilitate cleaning of the wearer or the biosensor display.

In certain preferred embodiments, the article 20 also may comprise an actuator. As used in this application, the term "actuator" refers to a device that comprises "potential" and a means of transforming that potential to perform or activate a "responsive function." The potential of the actuator may comprise either stored or potential energy or stored material. The actuator thus may perform or activate a responsive function by transforming potential energy to kinetic energy or by releasing or delivering a stored material. A "responsive function" is defined for the purposes of the present invention as a function performed upon the body substance, the wearer, the article, or a component or components thereof, or a signal to the wearer or the caretaker. A component of body substance may include, for example, moisture, electrolytes, enzymes, volatile gases, bacteria, blood, etc. A component of the wearer may also include skin, genitalia, the anus, the anal sphincter muscle, etc. A component of the

article may also include leg cuffs. waist cuffs or other waste barriers and/or containment components. side panels. ears. a chassis. an absorbent core. an acquisition component, a fastening system. the longitudinal or end edges. etc. Potential energy may be stored as mechanical, electrical. chemical or thermal energy. "Kinetic energy" as used in this application refers to the capacity to do work or to perform a responsive function as described above (e.g.. expansion of a compressed device. rotation of a twisted device, a gel that moves as it changes phases. coating or treatment of skin or feces. inhibition of an enzyme, adjustment of pH. etc.).

Triggering the creation of a three dimensional structure to capture body substances, for example. involves responsive functions performed on a component of the article and, ultimately. on the body substances. Capturing body substances. wiping the skin of the wearer or treating the skin with a skin care composition. antimicrobial agent, antifungal agent or enzyme inhibitor, for example. are responsive functions performed on the body substances and/or the wearer. Adjusting the article's geometry (in one, two or three dimensions) or physical properties (e.g., bending modulus, geometry, etc.) are examples of responsive functions, which may be performed on the article. Signaling a caretaker and/or the wearer that an event has occurred, or is about to occur, is also considered a responsive function for the purposes of the present invention. The signal may be visual, auditory. tactile, electrical. chemical, or biological. An actuator of a disposable article may. for example, release or deliver a deodorant. enzyme inhibitor, antimicrobial agent. antifungal agent, skin care composition or pH control agent; capture, wipe, cover, trap, immobilize, seal, pump, or store bodily waste; or trigger the release or creation of a structure or element designed to perform one or more of these functions or any other responsive function upon the body substance, wearer, article, or a component thereof.

The actuator of the present invention may release potential energy to perform or activate a responsive function upon the body substance, the wearer. the article, or a component thereof. The release of potential energy may transform mechanical, electrical, chemical or thermal potential energy into mechanical. electrical or chemical kinetic energy to perform the responsive function. Actuators may be triggered by a

threshold level of an input to release potential energy to perform a responsive function or may respond continuously to an input as described below. For example, a compressed foam has stored compressive mechanical potential energy and may provide mechanical kinetic energy when it is released. A twisted foam has stored torsional mechanical potential energy that may provide mechanical kinetic energy, i.e., rotation, when it is released. In addition, stored chemical, electrical or thermal energy may be used to release electrical, mechanical, chemical or thermal kinetic energy. The actuator of a disposable article, for example, may include one or more of the following: stored lotion, anti-fungal or antimicrobial agents, feces modification agents, enzyme inhibitors, pH buffers, dyes, pressurized gas, a compressed foam, a twisted foam, a pump, a closed system liquid transport member, an electrically sensitive gel, a pH sensitive gel, a salt concentration gel, etc. Potential energy may be stored in any manner sufficient to maintain or restrain it until it is required. Suitable means for maintaining and/or restraining such energy include batteries and/or capacitors, elastically, torsionally, compressively tensioned materials or structures in the form of unreacted reagents, and materials capable of performing physical or chemical functions (e.g., absorbents, emollients, pH buffers, enzyme inhibitors, feces modification agents; compressed gases, etc.).

Alternatively, the actuator of the present invention may comprise a quantity of a stored material that has the capacity to perform or activate a responsive function upon the body substance, the wearer, the article, or any component or components thereof. In one embodiment, for example, the actuator may release or deliver a stored material that performs a responsive function. In this embodiment, the actuator may be triggered by a threshold level of an input to discontinuously release or deliver the stored material at a given time or may release or deliver the material continuously. The actuator may, for example, include stored lotion, skin care compositions, antifungal or antimicrobial agents, feces modification agents, enzyme inhibitors, pH buffers, dyes, etc. In certain preferred embodiments, the material may be delivered by an actuator such as an expanding resilient material, a released high pressure gas, etc.

Figures 2 and 2A illustrate an actuator 90 comprising a compressed resilient material 94, such as a foam, sealed under at least a partial vacuum within a pressure differentiation device 91. A pressure differentiation device, as used herein, is any device or structure that can maintain a resilient material in a compressed state (e.g., can store energy by providing a constraining pressure on the compressed resilient material 94). A "compressed state" is defined as the condition in which a material is maintained at a smaller volume than the material would have if unconstrained and under zero applied pressure. With respect to resilient materials, a compressed state may generally be achieved by applying a pressure to a surface of the material or via any other means known in the art. The pressure differentiation device may, for example, comprise a vacuum sealed bag or tensioned materials, such as elastic or inelastic bands or strands, strips, films, nonwoven, scrims, or foams, that constrain a resilient material. Preferably, the compression of the resilient material maintained by the pressure differentiation device 91 may be at least partially reduced (i.e., the compressed resilient material 94 may at least partially expand) via a trigger mechanism. A trigger mechanism is any element or device, such as a sensor, actuator, or combination thereof, that responds to an input to effect the equalization of pressure in the pressure differentiation device 91 and allow the compressed resilient material 94 to at least partially expand. Upon release of the compressed material, such as when a target biologically active analyte is detected, the compressed resilient material may expand and deliver the stored material. In some embodiments, it may be advantageous for the actuator 90 to comprise a void space 96.

The resilient material 94 may comprise any resilient material, including but not limited to, an EVA foam such as the ones available from Foamex Corporation of Eddystone, Pennsylvania identified as SIF/210PP1 or Aquazone 80A foam, or from Sentinel Products Corporation of Hyannis, MA identified as MC1900 EVA 2 lb/ft^3, or a HIPE foam as described in United States Patent No. 5,260,345 entitled "Absorbent Foam Materials For Aqueous Body Fluids and Absorbent Articles Containing Such Materials" issued to DesMarais et al. on November 9, 1993; United States Patent No. 5,387,207 entitled "Thin-Until-Wet Absorbent Foam Materials For Aqueous Body Fluids And Process For Making Same" issued to Dyer et al. on February 7, 1995; and United States

Patent No. 5.625.222 entitled "Absorbent Foam Materials For Aqueous Fluids Made From High Internal Phase Emulsions Having Very High Water-To-Oil Ratios" issued to DesMarais et al. on July 22. 1997. (Each of the patents identified above is incorporated by reference herein.)

In some embodiments of the present invention. the pressure differentiation device 91 may comprise a bag. such as soluble bag 92. The soluble bag 92 may be soluble in the presence of one or more different types of input. such as water, urine. fecal enzymes, a pH level. etc., and may have physical and/or chemical characteristics (e.g.. thickness) that may be designed to set a threshold level of that input required to dissolve the bag. The soluble bag may, for example. comprise a plastic film that is soluble to water such as PVA films supplied by Chris-Craft Industrial Products. Inc. of South Holland. IL as MONOSOL M7031, M7030, M8630, M8534. or E6030 film, or H. B. Fuller Company of St. Paul, MN as HL 1636 or HL 1669-X. The film thickness, for example, may also be modified to provide a desired activation. The film used may, for example, also have a thickness in the range from about 0.0005 to about 0.0015 inches. An HL 1636 film having a thickness of about 0.001 inches, for example, will activate with a moisture content of about 0.049 grams per square inch.

The actuator may alternatively comprise an electrically sensitive gel. Electrically sensitive gels are polymeric gel networks that, when at least partially swollen with water, change volume and/or geometry under the application of an electric current or field. For example, certain partially ionized polyacrylamide gels will undergo anisotropic contraction of about 50 % under weak electric fields (e.g., 0.5 volts/cm) when immersed in acetone and water. Alternative electrically sensitive gels may undergo electrically induced bending in the presence of water and a surfactant or may undergo an oscillating wave motion when subjected to an oscillating electric field. It is believed that local shrinkage may be induced in a portion of the gel, e.g., one side of a gel element, by concentrating positively charged surfactant molecules on the negatively charged gel polymer in an electric field. Changing the intensity and/or the polarity of the field induces a movement in the gel as one side decreases in length (e.g., a gel formed in a strip may curl). Electrically sensitive gels may comprise variable geometries such as

rectangular, circular, reticulated grid, etc. patterns in order to provide a valve to release a material, allow a body substance to flow through, prevent a body substance from flowing through, encapsulate a body substance, etc. as they change volume and/or geometry. An electrically sensitive gel formed in a strip, for example, may be bent to provide an available void space for when electrical activity in the external anal sphincter muscle predictive of defecation or urination is detected.

In Figures 5A and 5B, for example, a strip of electrically sensitive gel 494 is shown in a circuit in which fecal moisture may bridge the contacts 485 and allow current to flow to the electrically sensitive gel either bending or straightening the strip. Alternatively, an electrically sensitive gel 594 formed in a reticulated grid pattern 595, such as shown in Figures 6A, 6B and 6C, may be electrically induced to swell or shrink when an imminent urination is detected to form a valve that allows and/or prevents urine flow to another portion of the article 20. Figure 6A, for example, shows a circuit including a reticulated grid pattern of an electrically sensitive gel. Figures 6B and 6C further show a microscopic view of the grid in a shrunk and in a swelled configuration, respectively. An exemplary material is a weakly cross-linked PAMPs gel (poly(acrylamido-2-methyl propane) sulphonic acid). This type of gel may perform various functions such as applying or delivering a chemical feces treatment agent. Other exemplary electrically sensitive gels are described in United States Patent No. 5,100,933 issued to Tanaka on March 31, 1990 and WO 9202005, both of which are incorporated by reference herein. Alternatively, pH sensitive gels or salt concentration sensitive gels that change volume and/or geometry at specific pH or salt concentrations, respectively, may be used as an actuator of the present invention.

The actuator may be disposed in and/or operatively connected to any portion of disposable article that will allow the actuator to perform a responsive function upon the body substance, the wearer, the article, or a component thereof. In article 20, for example, the actuator may be located in the front waist region 36, the rear waist region 38 or the crotch region 37 of article 20, and may be integral with, disposed adjacent to or joined to a component of the chassis 22, the topsheet 24, the backsheet 26, the absorbent core 28, side panels 30, leg cuffs 32, a waist feature 34, a fastening system 40, the

longitudinal 50 or end 52 edges. etc. The actuator may also be completely contained within the article such as article 20. may have a portion located in the article and a portion located outside the article 20. or may be completely external to the article 20. An actuator or a portion of an actuator may be operatively connected to one or more biosensors 60. one or more controllers 80. another portion of the actuator or another portion of the article 20. Further. the actuator may be integral with the article 20. or may be installed by the caretaker or the wearer.

The article 20 may also include a controller. A "controller" is defined for the purposes of this application as a device that receives an input from a biosensor and determines if one or more actions are to be taken. The controller may receive a signal from the biosensor 60 and direct the actuator to perform a responsive function upon the body substance. the wearer. the article or a component thereof. Alternatively, the actuator may receive the signal directly from the biosensor 60 and perform a responsive function upon the wearer, the body substance, the article or a component thereof. The controller may include materials that undergo chemical or physical change, may be a chemical, mechanical or electrical device that processes information from a biosensor, etc. The controller may include a transducer comprising a polylayer Langmuir-Blodgett film, wherein one or more layers includes a bio-recognition element. Upon contact with water, Langmuir-Blodgett films are known to spontaneously reorganize, resulting in regions with more layers than the original film and other regions having fewer layers. This reorganization may expose the bio-recognition element to the environment preferentially in the presence of water, such as in a body substance, which may contain the target biological analyte. Thus, the number of false positives can be reduced and the shelf-life of the biosensor can be extended. Alternatively, an electrical controller that receives signals such as electrical potential from an electrochemical biosensor may receive and monitor multiple electrical signals and may repeatedly trigger the actuator. The controller may be integral with the biosensor component. integral with the actuator component, or a separate component of the system.

The controller may be disposed in and/or operatively connected to any portion of an article that will allow the controller to receive a signal from the biosensor 60 and to

provide a signal to the actuator. In article 20, for example, the controller may be located in the front waist region 36, the rear waist region 38 or the crotch region 37 of article 20, and may be integral with, disposed adjacent to or joined to the chassis 22, or a component of the topsheet 24, the backsheet 26, the absorbent core 28, side panels 30, leg cuffs 32, a waist feature 34, a fastening system 40, the longitudinal 50 or end 52 edges, etc. The controller may be integral with the article 20, or may be installed by the caretaker or the wearer. The controller may be completely contained within the article such as article 20, may have a portion located in the article and a portion located outside the article, or may be located completely outside the article 20. The controller or a portion of a controller may be operatively connected to one or more biosensors 60, one or more actuators 90, another portion of the controller or another portion of the article 20. The controller, for example, may receive a signal from the biosensor 60 and provide a signal to the actuator, e.g., by a radio frequency (rf) transmission.

Although distinct structural elements may perform the biosensor 60, actuator and controller functions, the biosensor 60, actuator and/or controller functions of the present invention need not be performed by distinct structural elements. The biosensor 60 and controller functions, for example, may be performed by the same structural element.

A "responsive system" is defined for the purposes of this application as a system that includes a biosensor 60 and an actuator that acts upon the body substance(s), the wearer, the article, or a component or components thereof when the biosensor 60 detects the appropriate triggering input. Upon sensing a given input parameter, the actuator effects the release of stored energy or the release or delivery of stored material to perform a responsive function. For example, when a proactive biosensor 60 including a transducer detects an impending event, the transducer provides a signal to the actuator effecting the release of stored energy. By detecting an input signal prior to the impending event, a responsive system in the article may be triggered to prepare for the event or to signal the caregiver or the wearer of the impending event. This allows construction of articles in which the body substance-management or treating technology is initially "hidden" or unobtrusive, but which is available at, or just before, the moment of need and/or in which the article may provide the caregiver or the wearer the opportunity to

prepare for an event in advance (e.g., administer a prohylactic treatment to the wearer in the event of detected pathogenic microorganisms or residual fecal contamination). Regardless of the specific input, the biosensor 60 in these embodiments may trigger an actuator to perform an action on the article, the wearer or the environment to prepare for the occurrence of the event or provide a signal to the caregiver that the impending event is about to occur. If the biosensor 60 comprises a sensing system, one actuator may be triggered by different biosensors and/or signals, or different actuators may be triggered by different biosensors and/or signals. Alternatively, one biosensor and/or signal may trigger multiple actuators.

A responsive system may respond in either a "continuous" or a "discontinuous" manner. As used in this application, a "continuous responsive system" refers to a responsive system in which the output is quantitatively dependent upon the quantity of the input, i.e., continuously increasing quantities of the input are required to effect continuously increasing quantities of the output, or where the output of the responsive system comprises a passive release of a stored material. A super absorbent polymer placed in an absorbent core of an article, for example, provides a continuous response in which the output is quantitatively dependent upon the quantity of the input, i.e., as increasing quantities of liquid body substances contact the super absorbent polymer, an increasing amount of the polymer contains that liquid until the capacity of the polymer is exhausted. A stoichiometric chemical reaction is another example of a system having a continuous response to increasing output. In the reaction A + excess B $\rightarrow$ C, for example, the amount of excess B converted to C is stoichiometrically and, therefore "continuously," related to the amount of A available in the system.

A "discontinuous responsive system" of the present invention, however, refers to a responsive system that has an output function that is essentially independent of the quantity of the input beyond a threshold level. For example, when one or more threshold levels of a given input are met, the responsive system may release all or a pre-designated portion of its stored energy or deliver, i.e., actively transport, all or a pre-designated portion of its stored material to perform a specific responsive function. In an ideal embodiment of the present invention, the output function, f(x), includes a "step" function

as shown in Figure 3A. In this embodiment, the rate of change in the output with increasing levels of input (d(output)/d(input)), i.e., the slope or first derivative f'(x) of the output function f(x), is preferably essentially zero when the amount of input is above or below the threshold level. At the threshold level, however, the d(output)/ d(input) rate of change preferably approaches infinity. Thus, in the ideal discontinuous response, the limit of the function f(x-ε) as ε→0 is not equal to the limit of the function f(x+ε) as ε→0, i.e., $\lim_{\varepsilon\to 0} f(x-\varepsilon) \neq \lim_{\varepsilon\to 0} f(x+\varepsilon)$.

The present invention, however, recognizes that in the physical world an ideal instantaneous step change at the threshold level is not necessary and may not even be possible in many instances. In a preferred embodiment, it is only necessary that the output function have a virtual step change with very little change in the input at or around the threshold level of the input. Thus, the present invention contemplates a discontinuous responsive system of the present invention having an output function that responds in a sufficiently discontinuous manner in the transition region such that the output function has at least a minimum relative degree of steepness in the transition region. While not wishing to be limited to a particular method of describing or modeling a discontinuous system, in a preferred method of determining whether a given output function performs in a sufficiently discontinuous manner as defined for the purposes of the present invention, the slope of the output curve at the inflection point is compared with the relative slope of a line between the first and last points of the transition region. For example, Figure 4A shows a graph of an exemplary output function, f(x) along with aligned graphs of the first, f'(x), and second, f''(x), and third, f'''(x), derivatives of the exemplary output function. The output function f(x) describes the effect of the in put (x or I) on the output or response (R(I)). For purposes of the present invention, the transition region is defined as the region between the relative maxima, $R(I_1)$, and the minima, $R(I_2)$, of the second derivative, f''(x), of the output function, f(x). The relative maxima, $R(I_1)$, and the relative minima, $R(I_2)$, are points at which the third derivative, f'''(x), equals zero. The inflection point, I_0, is defined as the point in the transition region at which the second derivative, f''(x), equals zero, i.e.,

$$\frac{d^2R}{dI^2}\Bigg|_{I=I_0} = 0.$$

The comparison of the slope of the output function at the inflection point to the slope of a line between the first and the last points of the transition region can be described by the equation:

$$\frac{dR}{dI}\Bigg|_{I=I_0} = k\,\frac{(\Delta R_T)}{(\Delta I_T)}.$$

In this equation dR/dI at the inflection point is the first derivative of the output function at that point. The term ΔI_T is the change in the input to the responsive system between the first, I_1, and last, I_2, points of the transition region, i.e., $I_2 - I_1$, and the term ΔR_T is the change in the response of the output function between the first and last points of the transition region, i.e., $R(I_2) - R(I_1)$. The coefficient k is a proportional constant that describes the relative steepness of the slope of the output function at the inflection point, I_0, compared to the slope of a line between the first and last points of the transition region. In order that the responsive system have a discontinuous output function, the proportional constant k must be at least about 2.0, preferably at least about 3.0, more preferably at least about 5.0, even more preferably at least about 10.0, with at least about 100.0 being the most preferred.

In certain embodiments, the relative degree of steepness in the transition region of a discontinuous responsive system may also be modeled by a transfer function of a control system having a series of an integer number, n, first order lags with an equal time constant. The transfer function of the responsive system is defined for the purposes of the present invention as the ratio of the Laplace transforms of the output (responding variable) to the input (disturbing variable). See, e.g., Robert H. Perry & Don Green, Perry's Chemical Engineers' Handbook, Sixth Ed., Chap. 22 (McGraw Hill, Inc. 1984). As shown in Figure 4B, the relative degree of steepness of an output function may be approximated by the formula: $KG(s) = K/(Ts + 1)^n$ in which KG(s) is the transfer function, K is a proportional element, T is the time constant of the system, and n is the

integer number of first order time lags. In this model, as the number n increases, the steepness of the output function in the transition region increases, and the model begins to approximate a discontinuous responsive system. Certain discontinuous responsive systems of the present invention preferably may be modeled by the above formula when n is greater than or equal to about 25, with n being greater than or equal to about 50 being more preferred, and n being greater than or equal to about 100 being the most preferred.

As shown in Figure 3A, a responsive system of the present invention may include a single threshold level at which the responsive system may release all of its stored energy to perform a specific responsive function or may include multiple threshold levels at which the system may release a pre-designated portion of its stored energy to perform one or more specific responsive functions at each of the threshold levels. In an embodiment having a single threshold level, for example, the responsive system may release all of its stored energy to perform the entire responsive function when that threshold level is met. In such a single threshold embodiment, In this example, the discontinuous responsive system includes a system that has two states such as on or off. When a threshold quantity of an input such as a target biological material is present in the absorbent article, the responsive system may perform a single responsive function upon the body substance, the wearer, the article or a component thereof, such as enveloping the body substance away from the skin of the user or providing an easily detectable visual signal to the wearer or caregiver. Thus, the discontinuous responsive system may perform a one-time "switch-like" function that changes from one state to another in the presence of a threshold level of an input.

Alternatively, as shown in Figure 3B, the responsive system may have multiple threshold levels at which when each threshold level is met the system may release a given "quanta" of energy or deliver a given quantity of material to perform a specific responsive function. In this embodiment, when each threshold level is met, a portion of the entire responsive function may be performed and/or different independent responsive functions may be performed in response to different threshold levels being met. For example, a responsive system may monitor a fecal enzyme and when each threshold

enzyme level is met may deliver an equal or unequal quantity of enzyme inhibitor(s) or lotion, or deliver a pH buffer at the first threshold level and perform another responsive function such as delivering a quantity of enzyme inhibitor(s) at the second threshold level. In each transition region, the responsive system responds essentially the same as the transition region in the single threshold embodiment described above.

In addition, a responsive system may monitor multiple inputs such as one or more pathogenic bacteria and/or one or more fecal enzymes and perform one or more responsive functions when the threshold levels of the different inputs are met or may perform one responsive function only when two or more of the threshold levels of the different inputs are met. Thus, a controller may monitor multiple different inputs and perform a different responsive function when the threshold level of the different inputs are met. Alternatively, the controller may perform a logic OR-gate type function such that a responsive function may be performed when one or more threshold levels of the multiple inputs are met. The controller may also perform a logic AND-gate type function such that a responsive function may be performed when each threshold level of two or more different inputs is met.

The responsive system may also comprise a "closed loop" or an "open loop" system. A "closed loop" system, which is also referred to as a "feedback control loop" system, includes distinct biosensor 60 and actuator components and performs a responsive function upon the input. In some preferred embodiments, the system may also use a detection or a measurement of an element or a parameter of the output condition as at least one trigger of the responsive function that is performed upon the input. The output condition may be the state of the input condition after the actuator has had the opportunity to perform a responsive function on the input condition. The responsive function may be performed when the output condition reaches a threshold level, or may be performed only when the output condition and one or more other conditions are met. Acting upon the input may include acting upon the element sensed, e.g., sensing a microorganism and acting upon the microorganism, or may include acting upon a composition of which the element sensed is an integral component, e.g., sensing a fecal bacteria and acting upon the fecal mass or residual feces on the wearer's skin As

described above, a feedback control loop system includes at least two distinct components: the biosensor 60 and the actuator. The biosensor 60 detects an event, or a parameter associated with that event. The actuator receives a signal and performs a responsive function on the input condition detected by the biosensor 60. The feedback control loop may further include a controller. In this case, the biosensor 60 may provide a signal to the controller, and the controller may direct the actuator to perform a responsive function upon the input condition. The controller may be a separate component of the responsive system or the controller function may be performed by the biosensor 60 and/or the actuator.

The feedback control loop may be "non-modulating" or "modulating." In a "non-modulating" feedback control loop responsive system the responsive system acts as a one-time switch in which the actuator performs a responsive function on the input when the threshold level of the output condition is met. For example, the biosensor 60 may detect the presence of or measure the concentration of a specific pathogenic microorganism, and the actuator may signal the caretaker of a potential incipient infection. In this example, the actuator acts upon the input detected by the biosensor 60. A "modulating" feedback control loop, however, includes a biosensor 60, an actuator and a controller. In a modulating feedback control loop, the output condition is monitored constantly or repeatedly, and the controller directs the actuator to perform a responsive function on the input in order to maintain the output condition at a desired set point or within a desired range or to provide a continuous measurement of the level or concentration of the target biological analyte.

An "open loop" system, however, is a system that responds to the input to perform a responsive function without using feedback, i.e., the output has no effect upon the sensed input entering the system. An open loop system may include a responsive system that has a single device that performs the functions of both the biosensor 60 and the actuator or may have distinct biosensor 60 and actuator components in which the actuator acts upon something other than the input. A super absorbent polymer placed in an absorbent core of a disposable absorbent article, for example, provides an open loop response because the polymer only includes a single device that performs the functions

of the biosensor 60 and actuator. Alternatively, an open loop responsive system may include a biosensor 60 that detects a body substance or a component of a body substance, and an actuator that performs a responsive function in a continuous or a discontinuous manner on something other than the input detected by the biosensor 60.

The present invention includes responsive systems that provide a discontinuous or continuous response, whether open loop or closed loop. Other responsive systems are described in United States Patent Application Numbers 09/106,424 entitled "Disposable Article Having A Discontinuous Responsive System" filed on June 29, 1998 (P&G Case Number 7197); 09/107,563 entitled "Disposable Article Having A Responsive System Including A Feedback Control Loop" filed on June 29, 1998 (P&G Case Number 7198); and 09/106,225 entitled "Disposable Article Having A Responsive System Including A Mechanical Actuator" filed on June 29, 1998 (P&G Case Number 7199), each of which is incorporated herein by reference.

An example of a diaper 20 of the present invention may include a responsive system that includes a biosensor 60 as shown in Figure 1 and an actuator as shown in Figure 2. In this embodiment, the biosensor 60 may comprise a transducer operatively associated with a bio-recognition element adapted to detect *E. coli* in feces. Upon the specific detection of a threshold level of *E. coli* by the bio-recognition element, the transducer signals the actuator with an electrical current. The article shown in Figure 1 may include an actuator that comprises a compressed resilient material 94 vacuum sealed under a water soluble film 91, as shown in Figure 2 (e.g., a PVA film). Upon receipt of the proper signal from the biosensor 60, the actuator may close a switch, for example may release a small amount of stored water to contact and dissolve the water soluble film 91. This results in the release of the stored mechanical energy in the compressed foam. The resilient material 94 expands and forms a spacer to provide void volume for the incipient feces. Alternatively, the switch closure may additionally release an antimicrobial to control the *E. coli* and/or a visible dye to signal the *E. coli* presence to the wearer or caretaker. In another embodiment, the responsive system may include an actuator that alerts the caretaker or the wearer of an impending event such as a diarrheal infection or a skin irritation (e.g., candidiasis).

Test Method

Response Factor Test:

With the Response Factor Test as described hereafter, the response of a quantitative sensor as a reaction to exposure to a specific substance or composition can be measured.

The specific substances or compositions for which this test is suitable include: fecal test material in aqueous solution having a concentration of 1 gram of fecal test material per 1 gram of physiological saline solution; fecal test material in test urine solution having a concentration of 1 gram of fecal material per 1 gram of test urine solution; test urine solution; a solution of skatole in physiological saline solution having a concentration of 180 micrograms of skatole per gram of physiological saline solution; physiological saline solution.

All measurements are carried at body temperature (37° Celsius). The method includes the following steps in the following order:

1) Record quantitative response of the sensor after exposure to physiological saline solution for 24 hours. The background response is the maximum recorded response.
2) Expose the sensor to specified substance or composition.
3) Record quantitative response of the sensor while sensor is still exposed to the specified substance or composition for 24 hours. Substance response is the maximum recorded response.

The Response Factor is obtained by normalizing the substance response with the background response. In case the Response Factor is smaller than 1, the reciprocal value of the Response Factor is reported as the Response Factor (i.e., the response may be inversely correlated with the input).

The disclosures of all patents, as well as any corresponding published foreign patent applications), and publications mentioned throughout this patent application are hereby incorporated by reference herein. It is expressly not admitted, however, that any

of the documents incorporated by reference herein teach or disclose the present invention.

While particular embodiments and/or individual features of the present invention have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention. For example, although aspects of the present invention is illustrated and described with respect to a disposable diaper, the present invention is not limited to this embodiment. The present invention may also be used, for example, in articles that are applied directly to a wearer (e.g., to the perianal or perineal regions of the wearer) prior to the application of a disposable diaper or in place of a disposable diaper, in a pull-on diaper, a diaper insert, a sanitary napkin, a tampon, etc. Further, it should be apparent that all combinations of such embodiments and features are possible and can result in preferred executions of the invention. The present invention may also include portions of the articles described herein which are useful independently of other features described herein. For example, the present invention may also include sensors and detectors, and methods of preparation of such sensors and detectors, and methods of using the such sensors and detectors, which sensors and detectors are employed for a particular purpose that has not been known previously, regardless of whether they are on an article of a specific type and regardless of whether they are used alone, or in the context of a diagnostic panel with other sensors. Therefore, the appended claims are intended to cover all such changes and modifications that are within the scope of this invention.

What is claimed is:

1. An article containing a detection device characterized in that it comprises:

a biosensor including at least one bio-recognition element, the biosensor being adapted to detect a target biological analyte in body substances, or on or through the wearer's skin,

wherein the article is selected from the group consisting of: a diaper, a training pant, a waste bag, a feminine hygiene device, a patch, a disposable wipe, a disposable towel, toilet tissue, and a liquid collection device.

2. An article according to Claim 1 of a type to be worn by a wearer, said disposable article comprising a diagnostic panel for detecting biological analytes in body substances or on or through a user's skin, the diagnostic panel including:

at least a first biosensor and a second biosensor, the first biosensor adapted to detect at least a first target biological analyte and the second biosensor being adapted to detect at least a second target biological analyte which is different from the first target biological analyte.

3. An article according to Claims 1 or 2 wherein the biosensors include bio-recognition elements comprising biologically reactive agents.

4. An article according to any of the preceding claims wherein at least one biosensor is selected from the group of: a biocatalytic biosensor and a bioaffinity biosensor.

5. An article according to Claim 4 wherein the bioaffinity biosensor is selected from the group of: a chemoreceptor-based biosensor and an immunosensor.

6. An article according to any of the preceding claims wherein at least one bio-recognition element is selected from the list including:

(a) an enzyme or sequence of enzymes; an antibody; DNA; an organelle; a membrane receptor protein; a natural or synthetic membrane; viable or nonviable bacterial, plant, or animal cells; at least a portion of a nerve bundle; at least a portion of a sensing organ; or

(b) *Acinetobacter baumannii* TOI36 and *Bacillus sp* TOI41; and

(c) the biorecognition element is preferably disposed on a substrate selected from the group of: polymer based materials, hydrogels, tissues, nonwoven materials, woven materials, and silicon semi-conductors.

7. An article according to any of the preceding claims wherein the biosensor detects target biological analytes selected from the following group: pathogenic bacteria, colonic bacteria, viruses, parasites, bacterial toxins, fungi, enzymes.

8. An article according to Claim 2, 3, 4, 5, 6, or 7 wherein at least one of the following properties applies to the diagnostic panel and the biosensors included in the diagnostic panel:

(a) the diagnostic panel is adapted to detect pathogenic causes of diarrhea;

(b) the first and second biosensors are each adapted to detect one or more viral causes of diarrhea and to provide an indication of the presence of the one or more viral causes to the user, a caretaker, or a health professional, and the viral causes preferably comprise at least one of the following group: rotavirus, astrovirus, calcivirus, adenovirus, and Norwalk virus;

(c) the first and second biosensors are each adapted to detect one or more bacterial causes of diarrhea and to provide an indication of the presence of the one or more bacterial causes to the user, a caretaker, or a health professional, and the bacterial causes preferably comprise at least one of the following group:

EPEC, ETEC, EHEC, EIEC, EAEC, *Campylobacter jejuni*, *Vibrio cholerae*, and *Shigella* strains, including *S. sonnei* and *S. flexneri*.

(d) the first and second biosensors are each adapted to detect one or more pathogenic causes of diarrhea and to provide an indication of the presence of the one or more causes to the user, a caretaker, or a health professional;

(e) the first biosensor is adapted to detect at least one viral cause of diarrhea and the second biosensor is adapted to detect at least one bacterial cause of diarrhea; or

(f) the first and second biosensors are each adapted to detect one or more protozoan causes of diarrhea and to provide an indication of the presence of the one or more protozoan causes to the user, a caretaker, or a health professional.

9. An article according to Claim 2, 3, 4, 5, 6, 7, or 8 having at least one of the following additional features:

(a) at least one of the first or second biosensors additionally comprises a transducer, wherein the transducer is preferably selected from the group including electrochemical, optical, thermal, and acoustic transducers, wherein the transducer preferably signals only when target biological analyte is above a pre-defined threshold level;

(b) the article additionally comprises a cleaning element for at least one of the first or second biosensors;

(c) at least one of the first or second biosensors is affixed to a support element wherein the support element preferably adheres to the wearer's skin;

(d) at least one of the first or second biosensors is detachable from the article;

(e) the article further comprises an actuator that performs a responsive function when at least one of the first or second biosensors detects a target

biological analyte, and the responsive function is preferably a signal to a caretaker, or the wearer, wherein the actuator preferably transforms a potential energy to perform the responsive function, the potential energy being one or more selected from the group of: mechanical energy, electrical energy and chemical energy;

(f) the article further comprises a receiver, wherein the receiver is preferably integral with said article; or

(g) the article further comprises a transmitter.

10. An article for detecting the presence of vaginal infections or diseases according to Claim 1, 2, 3, 4, 5, or 9.

11. The article of Claim 10 wherein the biosensor detects various specific types of bacteria that may be the cause of bacterial vaginosis, including *Gardnerella vaginalis*, *Prevotella bivia*, *Bacteroides* species, *Mycoplasma hominis*, and *Mobiluncus* species.

12. An article for detecting the presence of vaginal infections characterized in that it comprises:

a diagnostic panel being adapted to detect non-specific types of bacteria that may be the cause of bacterial vaginosis,

wherein said article is selected from the group consisting of: a feminine hygiene device, a patch, a disposable wipe, a disposable towel, toilet tissue, and a liquid collection device.

13. The article of Claim 12 wherein the diagnostic panel detects the pH of the bodily fluid and the presence of amines in the bodily fluid.

14. The article of Claim 10 wherein the biological analyte is indicative of the presence of at least one of the following: yeast infections, a sexually transmitted disease, and *Trichomonas vaginalis*.

15. An article according to any of the preceding claims wherein at least one biosensor:

is provided on the body-facing side of a feminine hygiene device; and

comprises at least one sensor element that is covered with a covering element, wherein said covering element is preferably flexible.

16. The article of Claim 15 further comprising a wicking element adjacent said at least one sensor element for bringing body substances into contact with said at least one sensor element.

17. An absorbent interlabial device having a body-contacting surface and comprising an absorbent core, said absorbent interlabial device characterized in that it has at least two detection devices disposed in a spaced apart relationship on said body-contacting surface of said interlabial device, wherein one of said detection devices is capable of detecting a substance in urine, and at least one of said detection devices is capable of detecting a substance in menses.

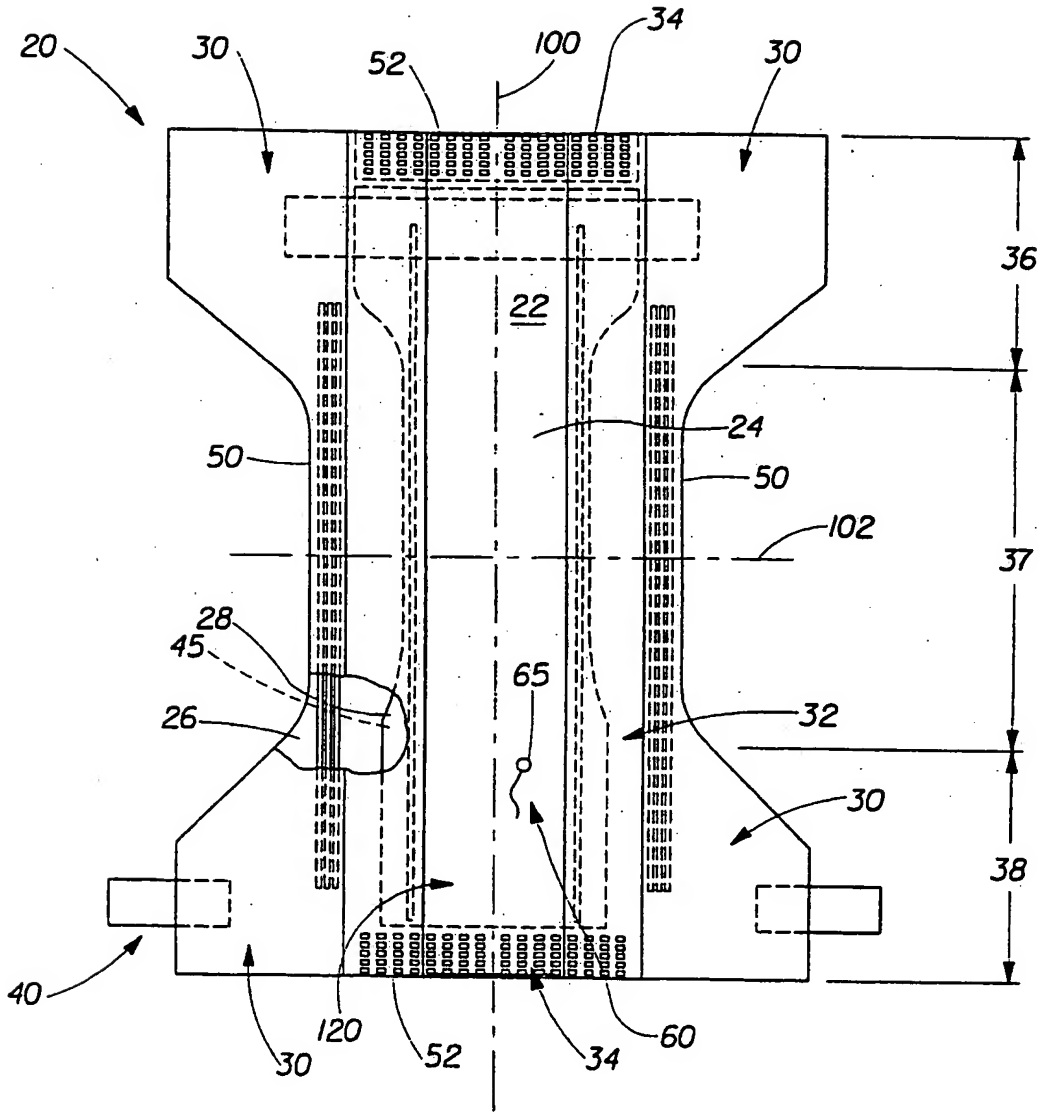

20
30
52
100
34
30
36
22
24
50
50
102
37
28
45
65
26
32
30
38
40
120
30
52
34
60

Fig. 1

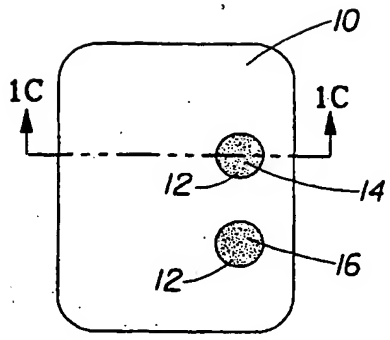


Fig. 1B

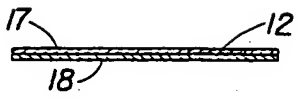


Fig. 1C

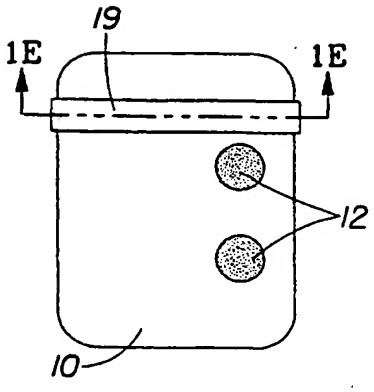


Fig. 1D

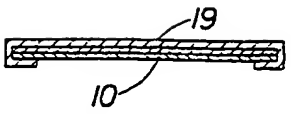


Fig. 1E

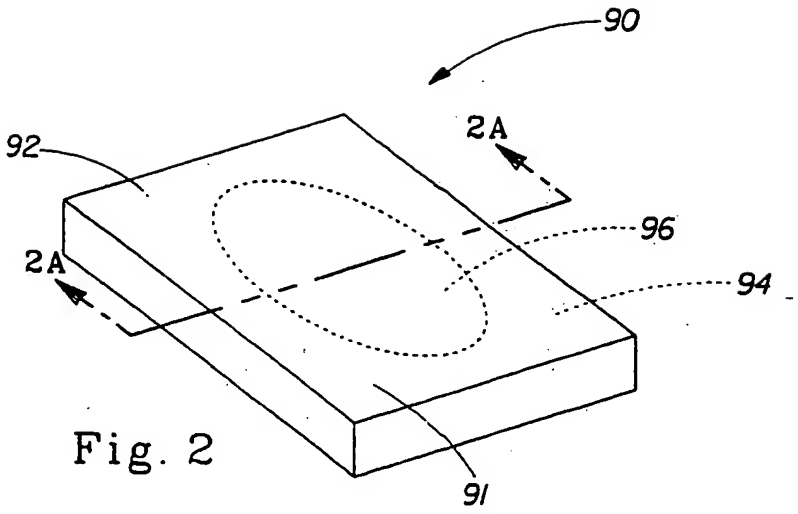


Fig. 2

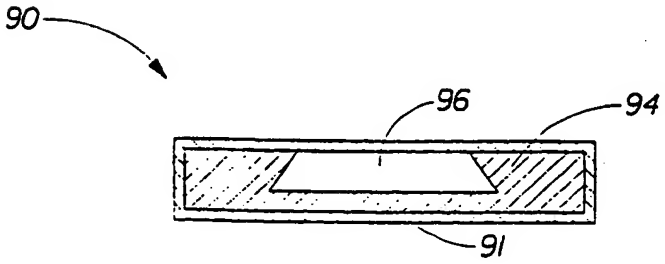


Fig. 2A

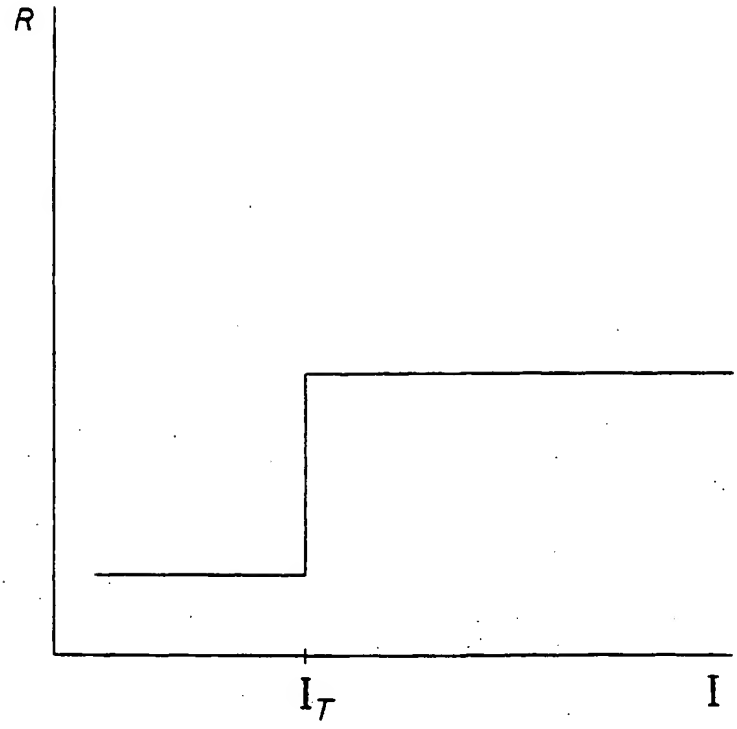
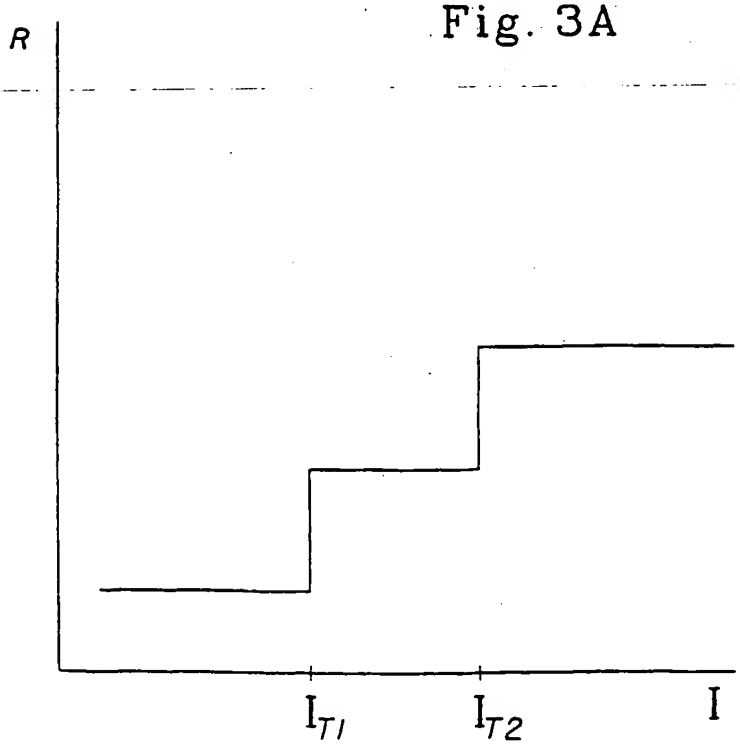


Fig. 3A



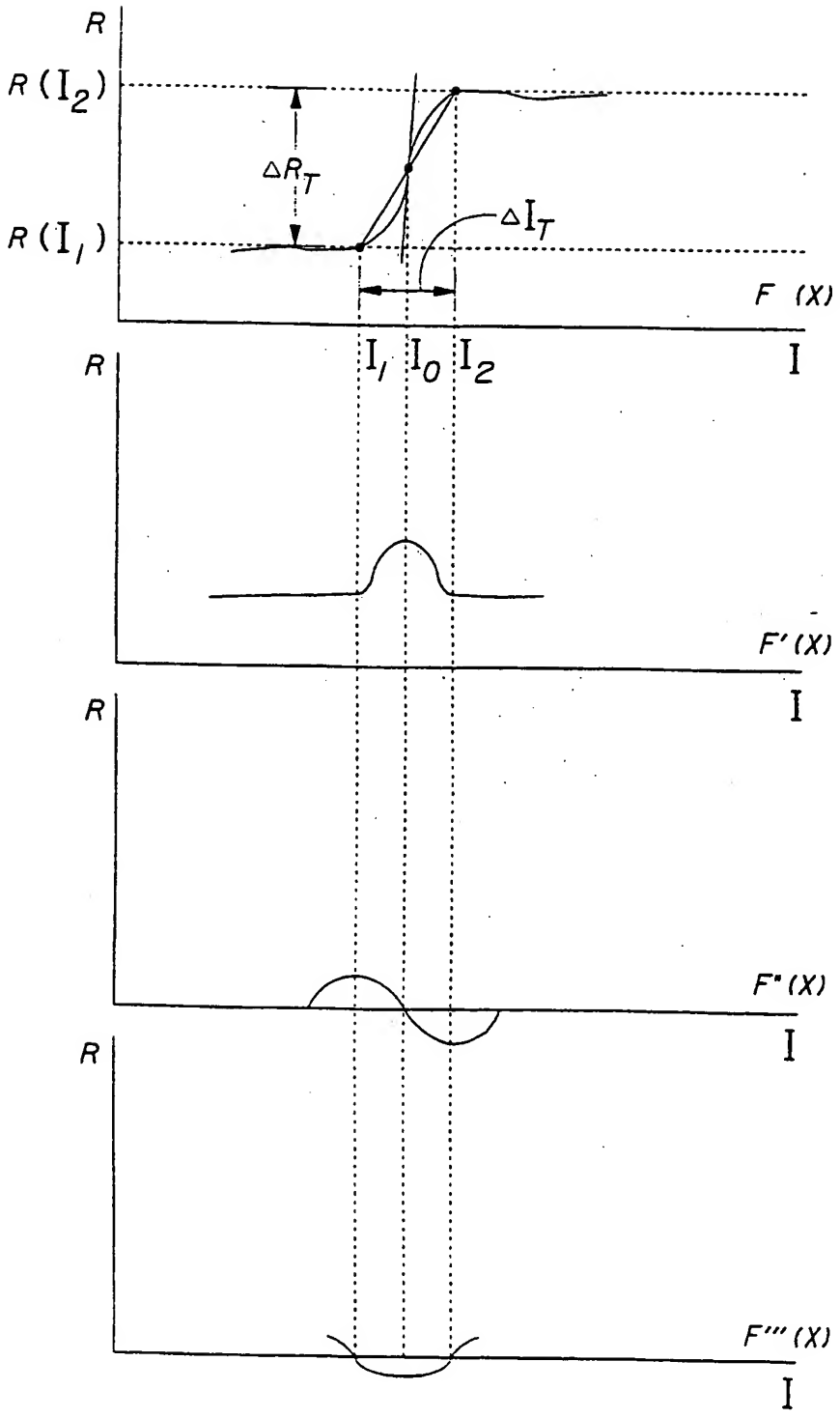


Fig. 4A

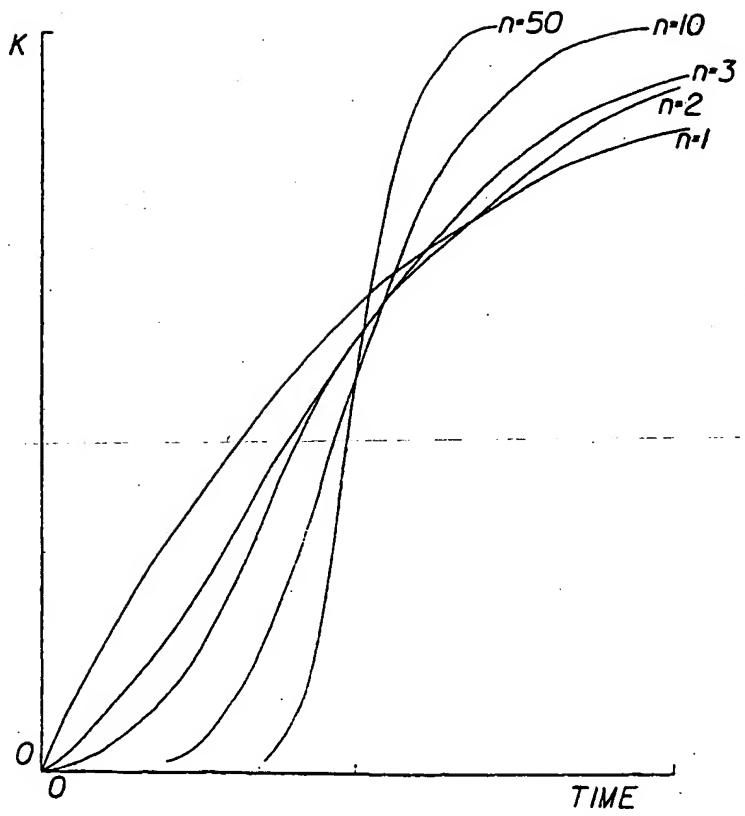


Fig. 4B

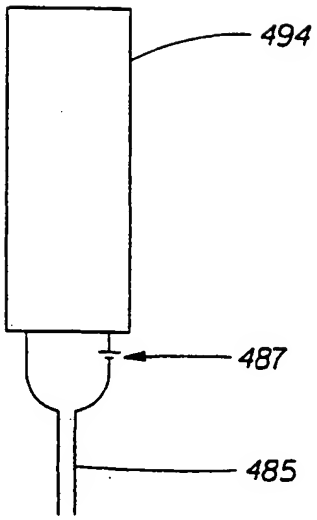


Fig. 5A

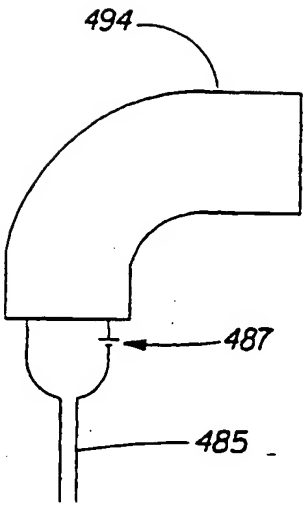


Fig. 5B

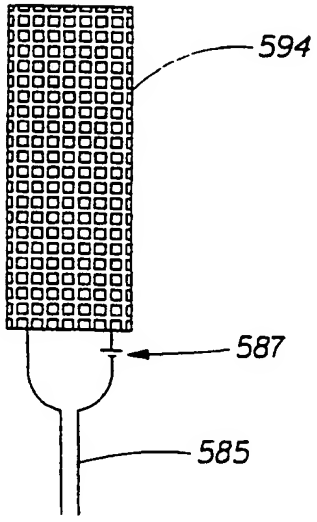


Fig. 6A

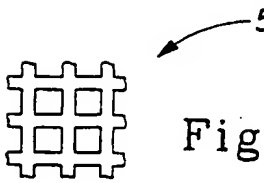


Fig. 6B

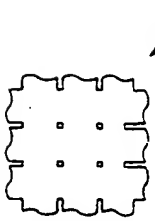


Fig. 6C

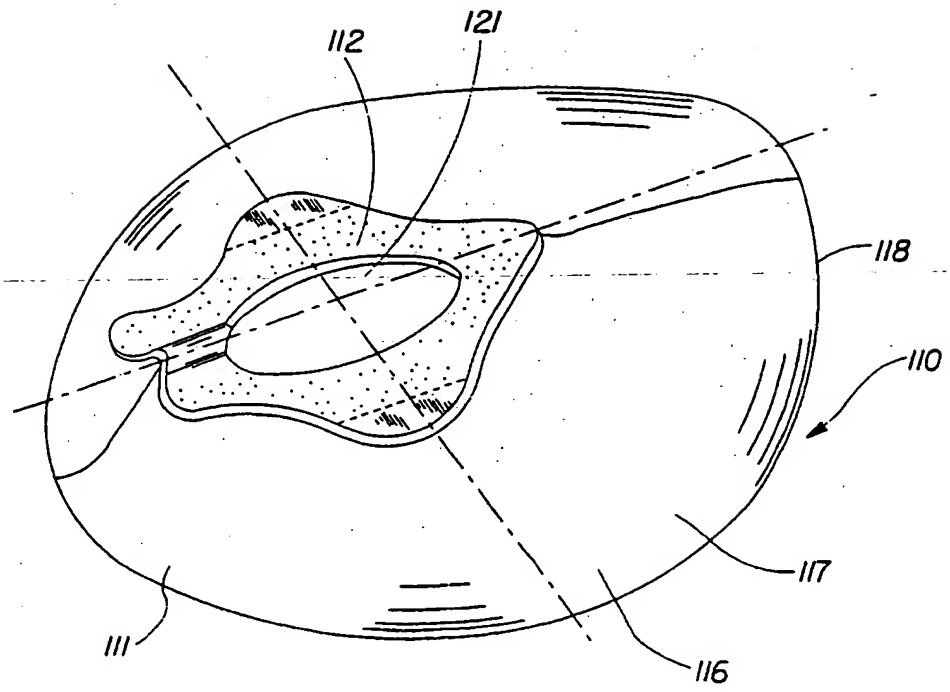


Fig. 7

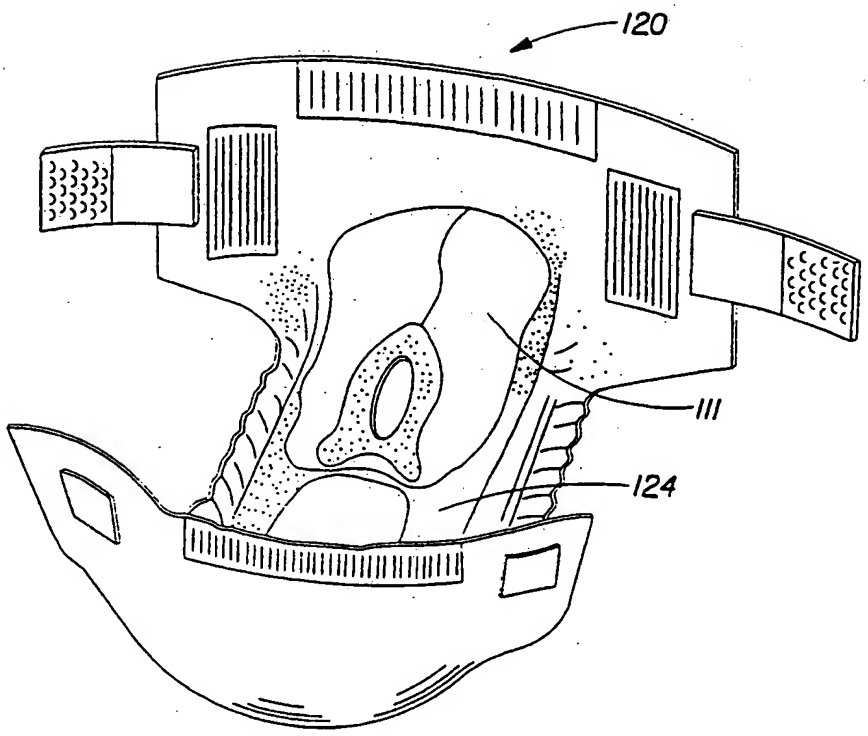


Fig. 8

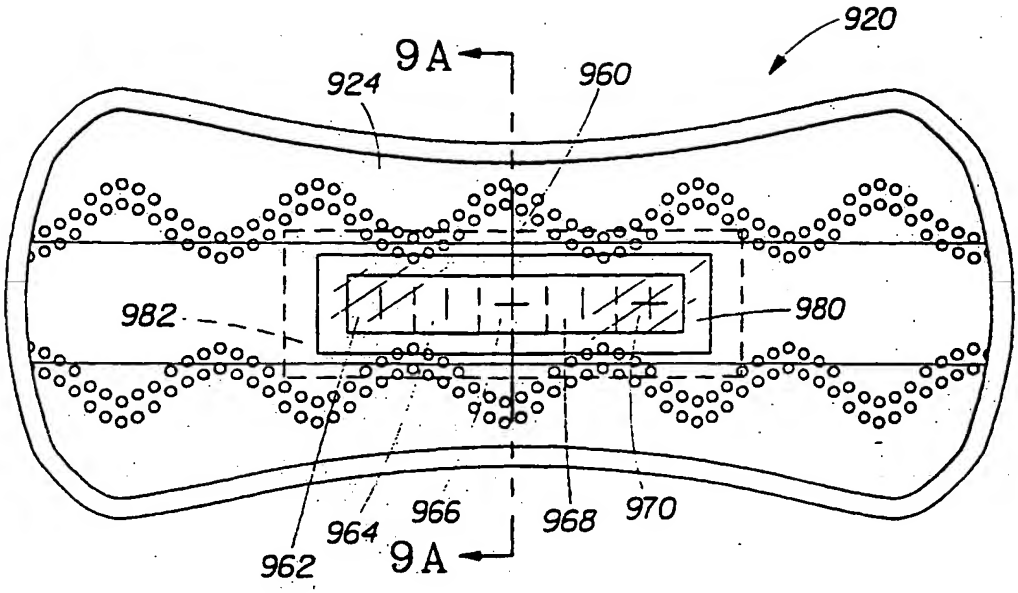

920
9A
924
960
982
980
962
964
966
968
970
9A

Fig. 9

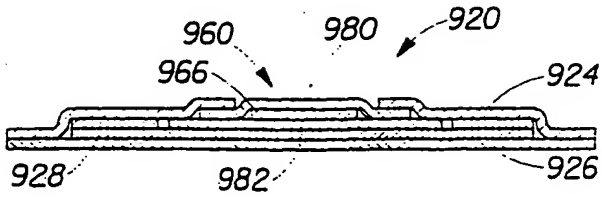

960
980
920
966
924
928
982
926

Fig. 9A

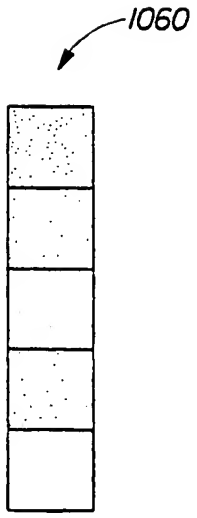


Fig. 10

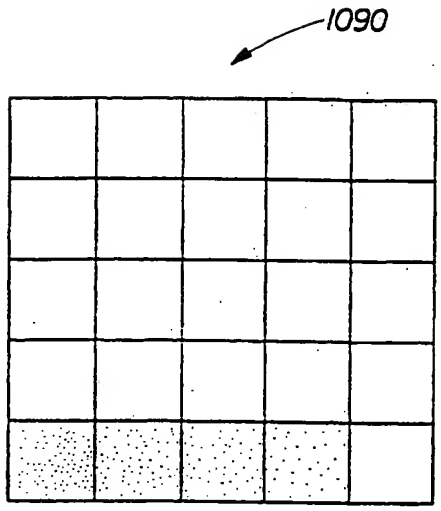


Fig. 11

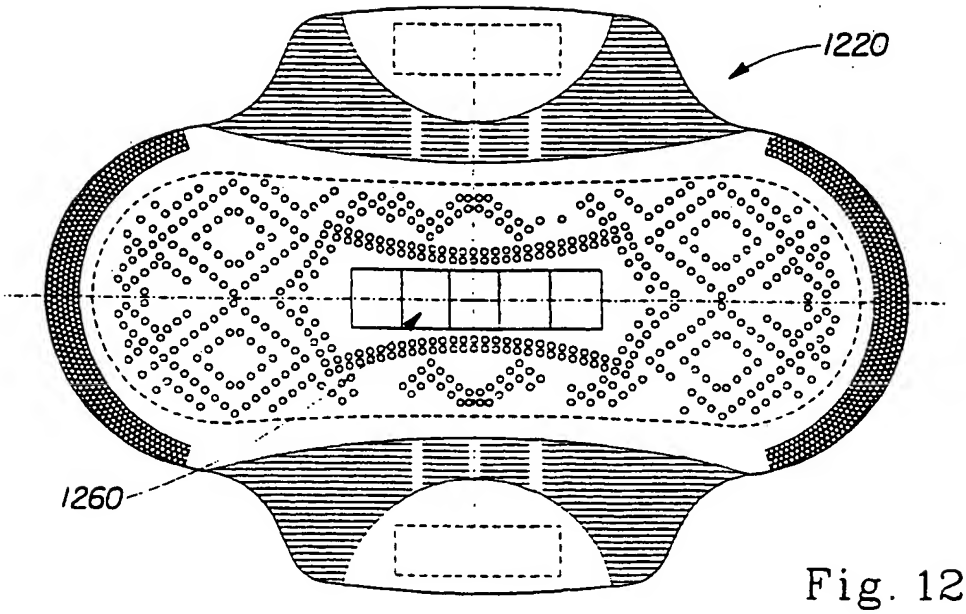


Fig. 12

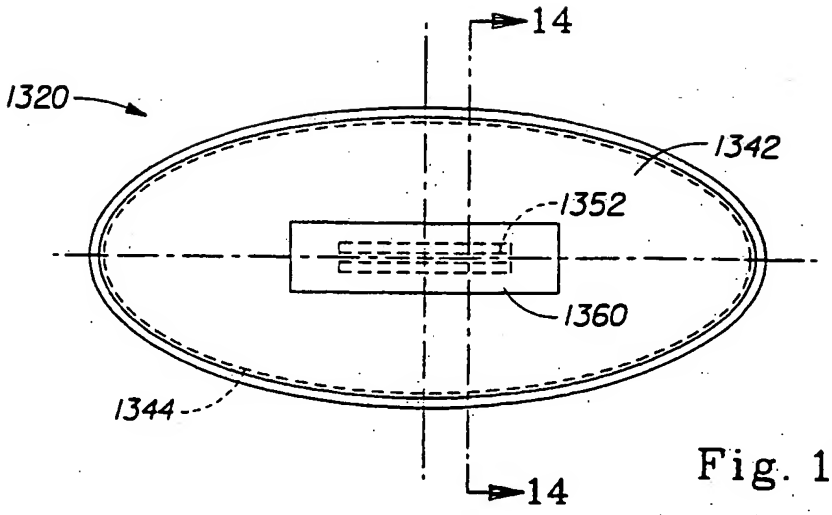


Fig. 13

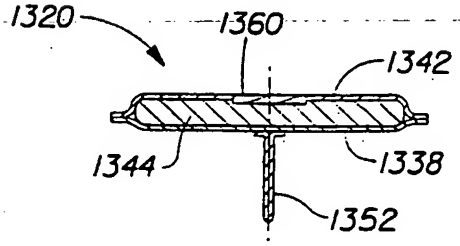


Fig. 14

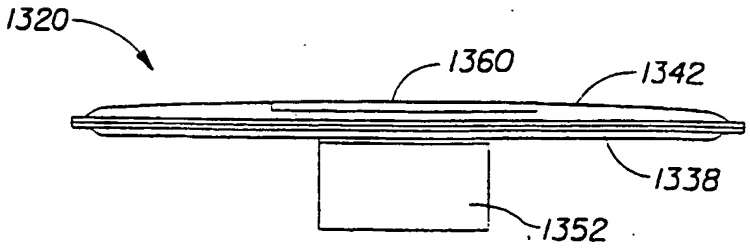


Fig. 15

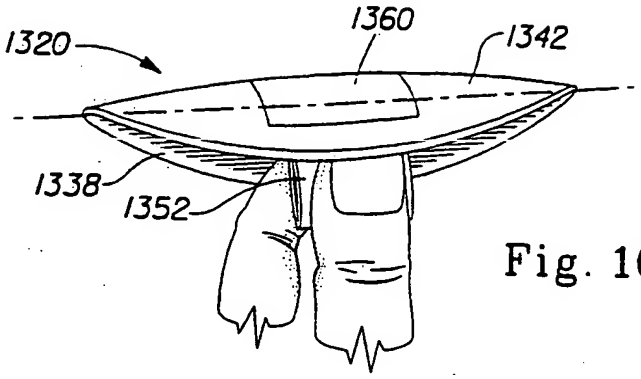


Fig. 16

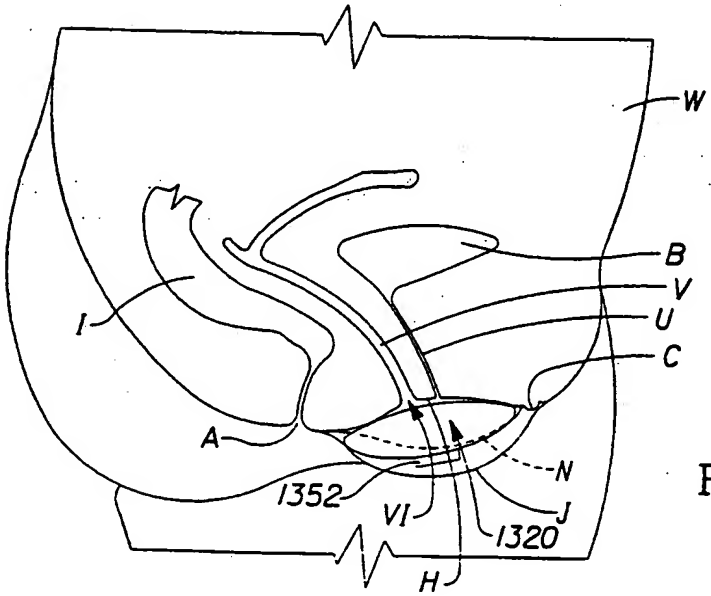


Fig. 17

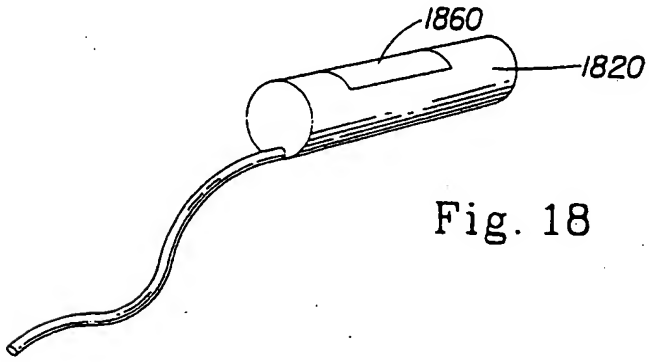


Fig. 18